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A Taxonomy of Regulations: The Effect of Regulation on Selling Activities

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**A TAXONOMY OF REGULATIONS: THE EFFECT OF REGULATION ON
SELLING ACTIVITIES**

by
John F. Riggs

A Dissertation

Presented in Partial Fulfillment of Requirements for the
Degree of
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**Coles College of Business
Doctor of Business Administration**

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The content and format of the dissertation are appropriate and acceptable for the awarding of the degree of Doctor of Business Administration.

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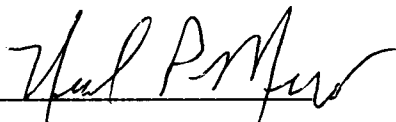
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ABSTRACT

Many companies are faced with rising numbers of regulations with which they must comply. Regulations are particularly common in the areas of employment, environmental protection, and licensing of businesses. In recent years, a growing trend of new regulations has emerged in the selling and sales management business environment, changing the nature and scope of salespeople's jobs. How do regulations affect the way salespeople do their jobs? This is an important and largely unexplored question. Therefore, the purpose of this study is to empirically construct a taxonomy of regulations that reveals their effect on current selling activities. A total of 7,493 observations were obtained from pharmaceutical representatives via an electronic survey which served as the basis for creating factor scores that were subsequently entered into a two-step cluster analysis. The analysis produced a six cluster solution of regulations indicating distinct taxonomic structures of regulations that affect selling activities. The resulting framework is useful to researchers, and practitioners, who can view regulations in terms of the degree to which selling activities are impacted.

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CHAPTER 1: INTRODUCTION

Many companies are faced with growing numbers of regulations with which they must comply. In fact, there are one or more government agencies that oversee virtually every part of a company's organizational chart. Regulations are particularly common in the areas of employment, health and safety, environmental protection, and licensing of businesses: Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), Equal Employment Opportunity Commission (EEOC), and the Federal Trade Commission (FTC) are examples of agencies responsible for regulating such areas.

Costs associated with regulatory compliance have been reported to cause significant burden on companies (Becht, Mayer, and Wagner 2008; Hahn and Tetlock 2008; Laeven and Levine 2009; Nicoletti and Pryor 2006; Weidenbaum 1998). The seemingly wide spread growth of government regulations placed on businesses continues to generate noticeable concern in the United States. Since 1980, the number of pages of regulations in the Code of Federal Regulations has increased from around 1,000 pages to over 25,000 pages, a 25-fold increase.

Rob Portman, a United States Senator from the state of Ohio, reported that beginning in 2005, a 60 percent increase in pending federal regulations, represents the highest number recorded since the government kept count (U.S. Senate Committee 2011).

Today, there are 4,226 regulations in the pipeline (The Office of Information and Regulatory Affairs 2011) of which the government has identified that more than 800

affect U.S. businesses, an 11.9 percent increase over 2009. In a recent statement to congress, The Office of Management and Budget (OMB), in accordance with the Regulatory Right to Know Act (2000) produced a report that “summarizes estimates by Federal regulatory agencies of the quantified and monetized benefits and costs of major Federal regulations reviewed by OMB over the last ten years” (OMB, p.3). The details of the report estimated \$12.5 billion in annual costs by executive agencies to implement regulations. The Code of Federal Regulations (U.S. Government Printing Office, 2011) cataloged over 130,000 pages of regulations from just over 60 federal agencies. These figures estimated that federal agencies generated/issued approximately 4,000 regulations annually.

Despite the large number of annually issued regulations, virtually all the attention has focused on regulatory agencies and regulatory impact at the firm level (Djankov, McLiesh, and Ramalho 2006; Hahn et al. 2000; Hemphill 2006 Kolsarici and Vakratsas 2010). Such topics as compliance (Breux and Vail 2006; Hahn and Litan 2005; O'Reilly and Chatman 1986), legal (Hahn and Tetlock 2008; Peterson 1994), ethics (Bellizi and Bristol 2005; Cavanagh 2004; Ferrell, Fraedrich, and Ferrell 2006; Zoghbi 2010) and costs (Becht, Mayer, and Wagner 2008; Crain and Johnson 2001; Hahn and Tetlock 2008; Sidhu, et al. 2008) are discussed relatively frequently. However, regulatory control is finding its way into functional areas within the firm. For example, a wide variety of laws and sources regulate the marketing function, such as; antitrust laws designed to protect consumers against predatory pricing schemes, consumer protection laws that provide rules for product warranties and product liability, and intellectual property laws that address issues related to patents, trademarks, and copyrights (Gollin, 2008; Lamb,

Hair, and McDaniel 2011; Pressey and Ashton 2009; Winn and Jondet 2008). Despite these laws, adopted specifically to govern marketing, regulation is no longer unique to the marketing function

Prior to April, 2003, selling efforts by life sciences firms such as medical device, pharmaceutical, and biotechnology had experienced no formal regulatory control over their selling activities. However, on May 5th, 2003, the Office of Inspector General (OIG) issued the Compliance Program Guidance for Pharmaceutical Manufacturers which prohibited many previously conducted selling activities. This program sparked the beginning of a sequence of newly outlined controls, procedures, and regulations directed at selling activities and customer interactions of life sciences companies.

Most recently, additional regulatory control has found its way into the selling and sales management business environment as demonstrated by the 2009 Code on Interactions with Healthcare Professionals published by the Pharmaceutical Research and Manufacturers of America (PhRMA). The PhRMA Code is specific to the pharmaceutical industry and regulates how pharmaceutical products and related pre-launch activities are to be conducted between company representatives and customers. For the first time, complying with these codes requires salespeople to change the ways in which they conduct selling activities and perform their jobs (Code on Interactions with Healthcare Professionals 2009).

How do regulations affect the way salespeople do their jobs? This is an important and largely unexplored question. Although considerable research has been devoted to regulation of business at the firm level, companies need to understand the impact of regulations on the selling environment in order to evaluate potential opportunities and

threats during the decision process (Jones, Zoltners, and Weitz 2005). Regulations intended to control selling activities are not industry specific. Numerous selling activities are regulated in telecommunications, real estate, energy, tobacco, pharmaceuticals, and financial services (Stremersch and Lemmens 2009). Rationale for regulating various selling practices has been attributed to an increase in scrutiny by industry groups, federal regulators, and consumer watchdogs on the practice of promotion and personal selling. This increased scrutiny has resulted in a labyrinth of new laws, the issuance of revised rules, and the creation of specific agencies designed to enforce compliance (Danzon, Keuffel, and Rose 2005).

Given the current growth of regulatory control, and its potential impact on the selling environment, adjusting with innovative approaches and adapting to new selling processes is required for both practitioners and academic researchers (Jones, Brown, and Zoltners 2005). Furthermore, the analysis of regulatory effects on selling is significant since it may help regulators develop more effective policies. Therefore, by extending taxonomy research to the sales and sales management literature, this dissertation seeks to provide a means for organizing sales activities affected by regulations into classes or groups that will be amenable to systematic investigation and theory development.

The following describes the order of this paper. First, classification frameworks are examined coupled with background information on taxonomies. Thereafter, regulation in business is reviewed, and since selling activities are impacted by the presence of regulations (Corneliussen 2005), the literature on selling activities is given an overview. Then, a description of the method employed to analyze the impact of regulations on selling activities followed by results, discussion and conclusions will

complete this study. The next section of this paper deals with the literature related to the study.

CHAPTER 2: LITERATURE REVIEW

The Need for a Taxonomy

Sokal and Sneath (1963) reported some of the earliest work on empirical taxonomic schemes. They speculate that many fundamental advances in organizational and social sciences were founded on such schemes and are necessary for progress in science (Fleishman, Mumford, Zaccaro, and Stephen 1991). Additionally, taxonomies provide researchers the required framework for hypothesis generation (Messick 1989), vital structural components, and identify the foundation for theory development (Fleishman, Quaintance, and Broedling 1984).

Salespeople are faced with growing numbers of regulations that impact their selling activities. For example, three primary factors of selling; developing relationships, promotional activities, and entertaining (Moncrief, Marshall, and Lassk 2006) are all regulated at the Federal, State, or industry level in numerous industries. Hence, there are regulations on gift-giving, site access, customer provided meals, online events, grants, information sharing, and numerous other activities (Boedecker, Morgan, and Stoltman 1991; Corneliussen 2005). Examples include, Mount Sinai Medical Center's prohibition on gift giving of any value by its vendors, regardless of industry. Also, the Jackson Health System (JHS) in Miami, Florida, has a policy that requires; “all Vendor Representatives, prior to engaging in any conversation or communication, for the purpose of selling, marketing, or influencing a decision, must first become ‘registered’ with the County as a ‘lobbyist’” (JHS Guidelines 2007).

Another example is how the real estate industry regulates the sharing of information. Because Realtors are bound by certain laws and regulations (Fair Housing Act), they cannot tell clients everything they may want and need to know. Fair Housing laws describe the primary function of a real estate agent as connecting or matching customers with properties, not providing information about local household income, demographics and environmental factors, which is also referred to as “steering”.

The high quantity of multifaceted and vague regulations not only makes it difficult for companies to know when they are in compliance, but also how to make good business decisions. Since many of these regulations have the force of law, are costly to administer, and impact many of the activities used by salespeople, it is important that selling organizations are able to organize, understand, and comply with them. Therefore, the first step toward understanding the interaction between regulations and selling tasks is to develop an acceptable and usable taxonomy for scholars and managers (McKelvey 1975).

To achieve this undertaking, this research constructs an empirically-based regulations taxonomy. Clusters of federal and industry regulatory activities are the classification basis for examining their effect on selling activities. The taxonomy aims to provide a framework for novel investigation, expansion of theory, and development of strategy in the area of sales and sales management.

Taxonomies and Typologies

Approaches to Classification

Taxonomies and typologies are two commonly used conceptual classification systems (Smith 2002). A taxonomy is an "empirically derived classification of actual

objects based on one or more characteristics, as typified by the application of cluster analysis or other grouping procedures" (Hair et al. 2010). Bailey (1994) described that "a taxonomy uncovers patterns within a set of empirical variables, creating internally cohesive clusters or groups." Alternatively,

"a typology is a conceptually based classification of objects based on one or more characteristics. A typology does not usually attempt to group actual observations, but instead provides the theoretical foundation for the creation of a taxonomy, which groups actual observations" (Hair et al. 2010, p.486).

Thus, "taxonomies are inductive and based on data, while typologies are deductive based on theory and require testing for validation" (Hair et al. 2010).

Bailey (1994) describes advantages that accompany the development and application of taxonomies, many of which promote the current study. Data integration is assisted by taxonomies; their quantitative design provides more valid classifications than the subjective nature of typologies; in addition, taxonomies produce variables with more specific descriptions than typologies. However, Bailey (1994) warns that a taxonomy's efficacy can be restricted if the data quality is poor and its measures are incomplete. In addition, interpreting taxonomies can be tricky according to Bailey, and cautions researchers about issues related to inference and generalizing. However, "using careful measurement procedures, taxonomies often provide greater understanding of the classified phenomena due to their ability to group objects into (relatively) homogenous classes" (Bailey 1994).

A taxonomy, in its purest form, is an inductive method that attempts to avoid any *a priori* scientific conceptualization. Hence, the categories are determined by data. For scholars, the result is a fresh classification scheme grounded in reality (Bunn 1993).

Taxonomies in Business Research

Taxonomies in Business Research (Strategy, Buyer Behavior, Logistics, Sales)

Scholars have produced decades of research developing and applying taxonomies to comprehend how firms gain strategic insights (Bowen 1990; Earl 2001; Hambrick 1984; Morrison and Roth 1992), how buyers behave (Bunn 1993; Cannon and Perreault 1999), how sales forces contribute to organizational performance (Homburg, Jensen, and Krohmer 2008; Moncrief, Marshall, and Lassk 2006) or how organizations operate via logistics (Autry, Zacharia, and Lamb 2008; Hambrick 1984). One such example within the services marketing literature is Bowen's (1990) development of an empirically based taxonomy of consumer's perceptions of services. An interesting outcome from Bowen's taxonomy showed that service managers stayed in a particular industry their entire career. This implies that a narrow-minded approach to marketing may encumber creativity and innovation, and so marketing insight is limited if services marketers do not look outside of their individual industry. Because of this, a large number of typologies have been constructed for grouping services. However, prior to Bowen's work (cluster analysis) these conceptualizations had not been previously studied.

Building on past efforts to categorize buying processes and situations, taxonomical research is often used in consumer research (Bunn 1993). Understanding customer buying behavior involves a complex set of issues confounded by many situational factors (Cannon and Perreault 1999). For decades, research scholars and marketing managers agree that customers "frame" problems in their own way (Puto 1987) and follow self-guided "rules of thumb" to direct their actions in specific situations (Newell and Simon 1972). To cope with the complexities of situations and the quantity

of decisions needed to be made, the creation of buying pattern classifications (taxonomy) are central to sustaining research and the establishment of marketing programs that work (Bunn 1993). As an extension of efforts to create classification schemes of buying decisions, Bunn (1993) identified six prototypical "buying decision approaches" through an empirically based taxonomy development procedure, resulting in a framework that views customers segments from the perspective of four fundamental buying activities. The findings provide new variations allowing for conceptual extension of the literature as well as being useful to marketing managers and researchers alike.

In recent years, the growing number of websites where consumers purchase and resell products has generated a new area of consumer buying and consumption research; consumer-to-consumer (C2C) purchase and resell behavior. Chu and Liao's (2007) taxonomy of consumer online resale behavior defined and specified how various dimensions (i.e., "planned" or "unplanned resell") impacts consumer's behavior on purchase and resale decisions. The authors posit that by examining consumer online resale and purchasing behavior relationships, the taxonomy supplies a more comprehensive picture of online consumer behavior (Chu and Liao 2007).

Another area in business research that has a history of developing and applying taxonomies is business logistics. In all areas of today's market place, an increase in worldwide competition has burdened companies with an excess of supply over demand. Therefore, the opportunity to make bad supply chain decisions is more present than ever (Christopher, Peck, and Towill 2006). An obvious example can be made by examining the execution of "just-in-time" delivery choices. At the outset, "just-in-time" delivery may decrease inventory in the production facility, however transport costs and supplier

inventory may increase. At first, this type of decision appeared to avoid cost at one company, but could easily transfer increased costs to the supply channel as a whole. This example provides the foundation for why investigators have proposed various supply chain taxonomies to extend the present logistics research.

Jones (2005) proposes that as research in selling and sales management is developing, it is important to appraise the field's key models, theories, and activities. Furthermore, he argues that current selling and sales management research remains based upon decades old models and assumptions that "may need revision in light of rapidly evolving demands in the marketplace."

For example, the relationship between sales and marketing business units has been investigated by many researchers (e.g., Biemans et al. 2010; Guenzi and Troilo 2007; Homburg and Jensen 2007), however little is known about the existing varieties of marketing and sales configurations. By identifying constructs that compose marketing and sales structures, empirically identifying variations of marketing and sales configurations, and developing a taxonomy, Homburg, Jensen, and Krohmer (2008) illustrate how much variance exists between the attributes of marketing and sales roles. Their findings suggest that the strength of the relationship between marketing and sales, together with high levels of market knowledge, is the most successful framework.

The field of selling continues to be affected by changes in technology, customer relationship development, and increased competition, among other environmental factors. As such, the breadth and depth of professional sales positions, including the actual selling activities and behaviors of selling have also changed significantly (Moncrief, Marshall, and Lassk 2006). Moncrief argued

"that continuing to routinely cite old taxonomies as though they still adequately portray today's domain of selling simply is not good research, nor does it adequately allow sales organizations and their managers to advance successful selling and sales management in practice" (Moncrief, Marshall, and Lassk 2006, p.64).

In response to outdated published sales position taxonomies (McMurray 1961; Moncrief 1986; Newton 1973), Moncrief, Marshall, and Lassk (2006), developed an up to date taxonomy of sales positions that considered current selling activities and strategies.

By using an updated list of 105 sales activities that reflect contemporary selling activities, the author's identified six new categories compared to previous sales position taxonomies (e.g., McMurray 1961; Moncrief 1986; Newton 1973). Consultative seller, new business/channel development seller, delivery seller, sales support, and key account seller are selling categories that more accurately reflect present sales jobs and their related activities (Moncrief, Marshall, and Lassk 2006).

As demonstrated by the examples given, the importance of classification-oriented research helps scholars and practitioners organize otherwise unsystematic set(s) of complex phenomena by determining patterns and universal traits among groups.

McKelvey (1975) concludes his seminal article with,

"The basic inductive-deductive process of science does not work without the phenomena under investigation being divided into sufficiently homogeneous classes. Managers cannot use the fruits of science unless they first can discern which of all the scientific findings apply to their situation" (McKelvey 1975, p.523).

Because there are numerous approaches to the study of regulations, it is important to be explicit about the focus of this research. For the rest of this paper, I discuss the regulating efforts that are intended to facilitate marketing exchanges only, as it is these that are germane to this study. Areas of particular relevance include customer

interactions, presenting product information, competitive information sharing, entertaining customers, gift giving, and grants.

Building on the review of taxonomies in business, the next section explores regulation in business, specifically the areas of compliance and cost, including some discussion on their impact. The section concludes with current examples of regulations that control selling activities.

Regulation in Business

Compliance

In general, compliance is defined as “following” rules, requirements, guidelines, standards or laws. Regulatory compliance fundamentally refers to “following” business processes, procedures, and practices that are in agreement with sets of or agreed upon norms (Lu, Sadiq, and Governatori 2008). In recent years, high-profile corporate scandals involving companies such as WorldCom, Tyco, and Enron has produced new types of challenges for companies concerning compliance. For example, effective December 1, 2006, organizations are required to adapt their processes for electronically stored information (ESI) during legal proceedings to the new Federal Rules of Civil Procedure (FRCP). Consequently, all companies facing potential U.S. Court investigation must comply with the new FRCP at once in order to avoid monetary fines, unfavorable case rulings, and business loss.

In 2008, Microsoft Corporation, the largest software company in the world, was fined by regulators of the European Union 899 million Euros (1.15 billion USD) for noncompliance with a 2004 antitrust order (European Commission 2009). One year earlier, DaimlerChrysler failed to meet U.S. federal fuel efficiency standards resulting in

\$30 million USD fine (Environmental Protection Agency 2007). That same year, York International Corporation, a global maker of heating, ventilating, air-conditioning, and refrigeration products, was ordered to pay \$12 million USD for violations of the U.S. Foreign Corrupt Practices Act of 1977 (U.S. District Court 2007). These types of reports, whereby companies incur significant fines for regulatory noncompliance have become increasingly common, illustrate the importance of ensuring internal controls are in place to address compliance with laws and regulations (Scholz 1984).

To further illustrate this point, over 1,300 executives responded to a 2005 Ernst & Young survey stating that compliance with regulations exceeded “worms and viruses” as the most important item when setting information security policy. For this reason, corporations must make certain that personnel are conscious of and take steps to conform to applicable laws and regulations. In response, companies are implementing regulatory compliance frameworks that include compliance policies, standards, measures, and training programs. The intended benefits of such an approach include the assurance of corporate control of compliance activities, increased efficiencies, heightened worker awareness of compliance standards, and the reduction of legal and financial risks (Maignan, Ferrell, and Hult 1999).

Recently in 2010, the Food and Drug Law Institute (FDLI) approved disclosure legislation requiring life sciences companies (e.g., pharmaceutical, medical device and biotechnology) to report sales and marketing promotional expenses (FDLI 2011). This action is the basis for compliance professionals to ensure sales organizations value the significance of their activities and maintain compliance. According to the Food and Drug Law Institute (2011), employee training, updated policies and procedures, inspections,

and specific compliance strategies are necessary in today's highly regulated business environment.

Cost of Regulations

"Although regulations have no direct fiscal impact, they pose real costs to consumers as well as businesses" (Hahn et al. 2000). As recent as 2008, the yearly expenditure of federal regulations in the United States grew to more than \$1.75 trillion (Crain and Hopkins 2010). Of this amount, the annual direct burden on business is estimated at \$970 billion, or \$8,086 per employee (Crain and Hopkins 2010). Included in these costs are resources employed by government agencies to disseminate, monitor, and enforce regulations, as well as the compliance activities by firms (OMB 2009).

The development of benefit-cost analysis tools has been the government's response to the soaring monetary costs of regulation (Hahn and Litan 2005). From the perspective of improved efficiency, an example of benefit-cost analysis that enhanced the effectiveness of regulation was the 1981 analysis of phasing out leaded gasoline. This was the beginning of the Reagan administration's plan to eliminate lead in gasoline. At that time, Christopher DeMuth was the official in charge of reviewing the regulation, and stated:

"A very fine piece of analysis persuaded everyone that the health harms of leaded gasoline were far greater than we had thought, and we ended up adopting a much tighter program than the one we had inherited. At the same time, the introduction of marketable lead permits saved many hundreds of millions of dollars from the cost of that regulation" (DeMuth and Ginsburg 2010).

After several analyses, DeMuth and his colleagues reported that constricting the lead standard in gasoline suggested over \$15 billion (1983 dollars) would be saved over 4

years (Hahn and Tetlock 2008). Three areas contributed to the overall savings; vehicle maintenance, decreasing emissions, and reduction in lead-related health issues.

The prior example shows how regulation was improved by economic analysis. However, Morrison, Winston, and Watson (1999) reported how governments also implement regulations where costs exceed benefits. The Airport Noise and Capacity Act of 1990 was studied five years after its inception (1995), and was found to cost over \$5 billion in excess of its projected benefits. Unintended consequences of this regulation included the replacement of 27 percent of the aircraft from U.S. airports earlier than budgeted due to the new noise level limits. This unplanned replacement would cost about \$10 billion (1995 dollars).

The previous research suggests that estimating the payback and expenses of individual regulations is not always straightforward. As seen in the case of leaded gasoline, estimating payback can involve complex ways of thinking that connect fundamental science to the wellbeing of individuals to the cost of those effects. Likewise, expenditures are also complicated and hard to estimate since different companies will respond in dissimilar ways regarding the evolution of technology, as seen in the case of the Airport Noise and Capacity Act of 1990 (Morrison, Winston, and Watson 1999). Hahn (2005) concludes that "it can be quite difficult to estimate how regulatory policy will affect different segments of the population", signaling that the quality of analyses of regulation does not meet the basic standards of economic research.

Apart from direct monetary costs, Weidenbaum (1998) argues that firms face more subtle burdens as a result of regulations. Fundamental to these are effects on competitiveness, innovation, and output. From this viewpoint, cost is seen in terms of an

alternative that is given up as a result of a decision, suggesting that companies are willing to take a "slap on the wrist" and pay a steep fine for not being compliant with regulations because financially it is more profitable for the company. Kambhu (1989) notes when companies have the resources to challenge penalties or hide its noncompliance, elevating standards may drive compliance down, despite the consequences.

A common theme emerges from the various literatures on cost of regulations: The process of compliance is both costly and time consuming, and many businesses face significant challenges to keep up with the changing laws. The cost burden, both direct and indirect, appears to be unchanging and continues to be a hurdle for businesses to thrive and remain a vital part of our economy.

Regulation of Selling

The impact of regulations has received a lot of interest in finance and accounting (e.g., Becht, Mayer, and Wagner 2008, Laeven and Levine 2009, Melis and Carta 2010; Piotroski and Srinivasan 2008, Sidhu et al. 2008), economics (e.g., Disdier, Fontagne, and Mimouni 2008), as well as marketing (e.g., Friedman and Gould 2007, Kolsarici and Vakratsas 2010; Petty and Andrews 2008). However, prior business literature has ignored the role of regulatory requirements in illuminating its impact on selling activities. "The fact that sales forces represent a major investment for many firms, with the largest sales forces spending billions of dollars a year to deploy and support tens of thousands of direct salespeople and their activities" (Zoltners, Sinha, and Zoltners 2001), it makes this area of study particularly interesting to academia and practice (Reece and Ahearne 2010; Twomey, et al 2008).

Selling Activities and Behaviors

The one fundamental trait that all sales people have in common is the activity of selling. Regardless of the role or industry, sales people engage in selling activities and these activities can be identified readily. Common selling activities include; building trust with customers, sharing product information, overcoming objections, entertaining customers, and gift giving (Moncrief, Marshall, and Lassk 2006). Additionally, work by Reid, Plank, and Minton (1997) propose a useful means of conceptualizing sales as an interpersonal communication process. The authors identify getting information, giving information, and using information to reflect a communication orientation in selling behavior.

Reid, Pullins, and Plank (2002) operationalized and tested these measures of a salesperson's communication behaviors for different types of purchase situations. The authors reported that among the six purchasing situations used in their research; (1) casual, (2) routine low priority, (3) simple modified rebuy, (4) judgmental new task, (5) complex modified rebuy, and (6) strategic new task (Bunn 1993), differences were found in the persuasiveness of the salesperson (Reid, Pullins, and Plank (2002). This research suggests that a salesperson's selling behavior is affected by external/environmental situations, in this specific study by purchase situations.

Selling Activity Measure Development Procedure

The sales behaviors chosen for the current study were derived following the lead from several authors. The process began by using the 121 sales activities developed by Moncrief (1986) coupled with the model posited by Reid, Plank, and Minton (1997) that

defined salesperson behaviors as those involved in “getting” information, “giving” information, and “using” information. This view of sales behaviors is based on the observation that communication is fundamental to the selling process (Reid, Pullins and Plank 2002). Finally, the list was further refined from a series of personal interviews and focus group sessions with salespeople and sales managers representing banking (NAICS 521110), real estate (NAICS 531210), pharmaceutical (NAICS 325412), and automobile (NAICS 441110) industries because of their known high degree of regulation (García-Canal, and Guillén 2008).

Initial personal interviews were conducted at a large pharmaceutical company’s annual national sales meeting in central Florida. The firm’s Vice President of Sales was asked to randomly select six to eight associates from his sales organization to participate in a focus group discussion regarding selling behaviors and activities. The discussion was conducted in a hotel boardroom with three pharmaceutical sales representatives, two district sales managers, and one key account manager. Each of the participants was provided a list of Moncrief’s (1986) 121 selling behaviors and Reid, Plank, and Minton’s (1997) 31 sales behaviors. The participants were asked to “circle” the activities that they currently perform in their day-to-day job as a salesperson. Following this exercise, a “semi-structured interview” focus group was conducted that allowed the interviewer to probe and expand on the participant’s responses regarding the relevance each of the activities has on their day to day job as a salesperson.

In addition to the focus group, a series of three phone interviews were conducted with the Vice President of a major U.S. bank, an independent real estate agent, and the owner of an automobile dealership respectively. Prior to each call, the participants were

emailed Moncrief's (1986) 121 selling behaviors plus Reid, Plank, and Minton's (1997) 31 sales behaviors. Consistent with the focus group procedure, the phone interviewees were asked to review the lists for relevance and application by "circling" the activities they currently perform in their daily job as a salesperson. The interviewer individually facilitated a "semi-structured interview" with each of the participants to explore and develop the participant's responses.

Classification of Selling Activities

The classification of an inclusive set of sales activities is a key step in the taxonomy development process. Examining the general selling literature, Moncrief, Marshall, and Lassk (2006), and Reid et al. (2002) propose a useful inventory of selling behaviors/activities. In addition, by combining input from the focus group and personal phone interviews of industry experts, the sales activities selected for the present study were theoretically defined and developed as a means of identifying selling activities impacted most by regulations. Three categories of activities were identified; (1) activities that build relationships, (2) activities that facilitate the buying process (getting to buy), and (3) activities that aid planning (appendix 6).

The first category, "relationship building", is comprised of relational selling behaviors that commonly create strong buyer-seller bonds. Behaviors such as asking questions, listening, and participating in mutual disclosure have been shown to create a strong buyer-seller relationship (Crosby, Evans, and Cowles 1990). In addition, the regularity of person-to-person communication between the salesperson and customer in the form of customer follow-up has also been acknowledged as a key determinant of relationship building. Therefore, the "relationship building" selling activities category

includes four measures adapted from Reid, Pullins, and Plank (2002); (1) ability to ask probing questions, (2) listened to customer, (3) ability to make a charismatic presentation, and (4) ability to work well with other people involved in the purchase, plus a fifth measure, (5) follow up with customer, which was added by industry interview and focus group participants.

The second category of selling behaviors, “getting to buy”, includes activities that reflect a salesperson’s expertise, and relevant skills associated with knowledge of their market, product, customers, and competition. The salesperson, for example, may use their product knowledge to help customers link certain product attributes to their needs, answer customer objections, or differentiate his/her product or service from the competition. Therefore three “using information” behaviors and three “giving information” behaviors from Reid, Pullins, and Plank (2002) were combined to create the “getting to buy” category. The six “getting to buy” activities are; (1) gain participation and got customer involved in the sales presentation, (2) ability to use analogies and similes in his/her presentation to help customer see how it relates to his/her situation, (3) ability to link his/her product or service attributes to customer needs, (4) able to differentiate his/her product or service from the competition, (5) ability to do “homework” on customer, and (6) ability to handle objections raised by customer. Boles, Johnson, and Barksdale (2000) reported that a customer is not likely to invest the time or effort necessary to build a selling relationship with a salesperson who lacks expertise in his/her field.

The third and final category of selling behaviors is “planning”. The acts of business planning, pre-call planning, searching out new leads, and targeting activities

require significant amounts of salesperson time. Hence, a lack of planning forces some salespeople to choose the customer they see next based on irrational, spur of the moment, client pressures (Lodish 1971). For this reason, we combined four of Moncrief, Marshall, and Lassk's (2006) selling activities with two activities identified from our industry focus groups for a combined list of six "planning" behaviors in category three. They are; (1) search out new leads, (2) pre-call planning, (3) designing a sales plan, (4) administrative activities and documentation, (5) conduct targeting activities, and (6) business planning. Actual items are provided in Table 1.

Table 1
Sales Communication Behaviors Measures (adapted from Moncrief, Marshall, and Lassk 2006; Reid, Plank, and Minton 1997; industry interviews and focus groups)

<i>Relationship Building</i>	
(Reid, Plank, and Minton 1997)	<ul style="list-style-type: none"> • Ability to ask probing questions • Ability to ask situation questions to try and understand customer needs • Used questioning to assess customer needs • Ability to ask clarification questions • Listened to customer • Ability to make a charismatic presentation • Ability to work well with other people who are involved in the purchase
(Adapted from industry interviews and focus groups)	<ul style="list-style-type: none"> • Follow up with customer
<i>Getting to Buy</i>	
(Reid, Plank, and Minton 1997)	<ul style="list-style-type: none"> • Gain participation and got customer involved in the sales presentation • Ability to use analogies and similes in his/her presentation to help customer see how it relates to his/her situation • Ability to link his/her product/service attributes to customer needs • Could differentiate his/her product/service from the competition • Ability to do “homework” on customer • Ability to handle objections raised by customer
<i>Planning</i>	
(Moncrief, Marshall, and Lassk 2006)	<ul style="list-style-type: none"> • Search out new leads • Pre-call planning/ targeting • Administrative activities/ documentation
(Adapted from industry interviews and focus groups)	<ul style="list-style-type: none"> • Conduct targeting activities • Designing sales plan • Business planning

The preceding list of sales communication behaviors (Table 1), are classified as valid measures for examining the potential impact of regulations based on face validity ratings by industry experts that included theoretical and practical considerations via focus groups. From an objective perspective, the fact that each identified selling activity can be directly linked to some form of regulation further demonstrates the proposed list of

selling activities accurately represents the concept of interest; selling activities impacted by regulations. Three categories of activities were identified; (1) activities that build relationships, (2) activities that facilitate the buying process (getting to buy), and (3) activities that aid planning (appendix 6).

CHAPTER 3: METHODOLOGY

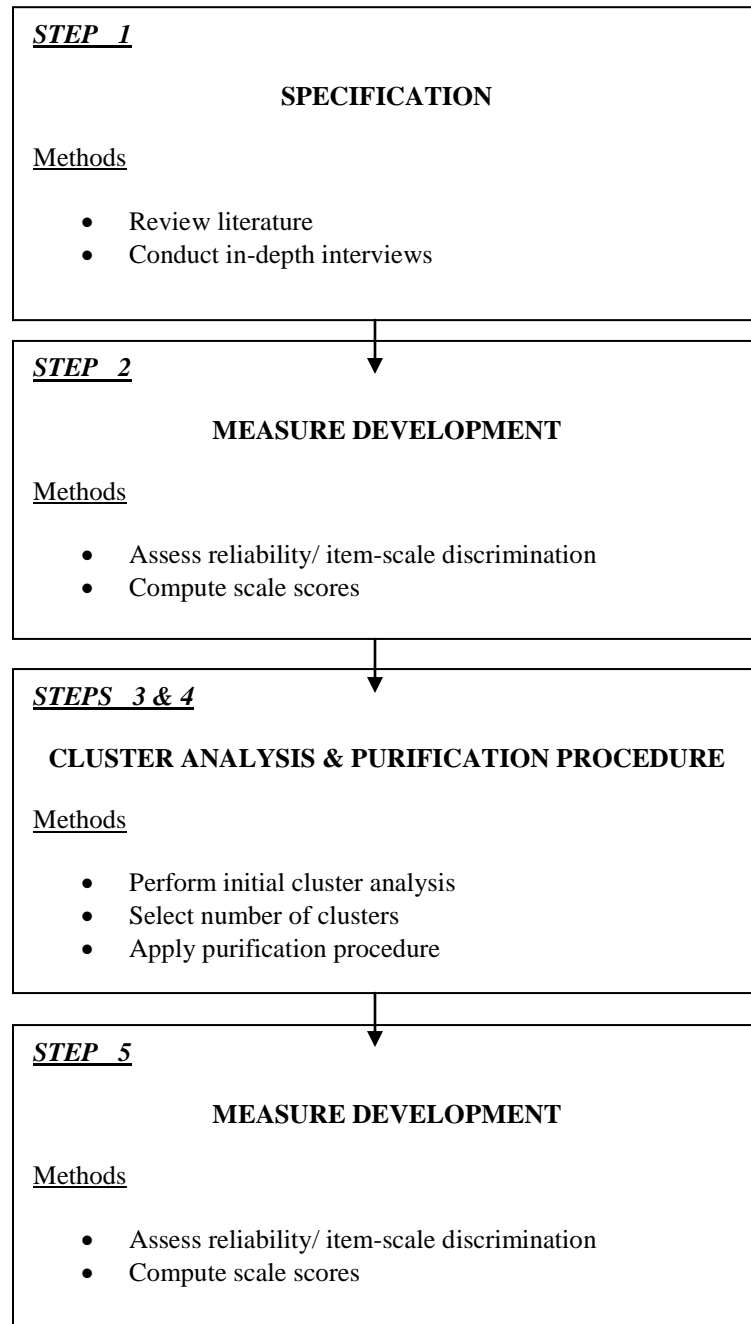
The approach used to build the current taxonomy of regulations that affect selling activities, is modeled after the commonly accepted practice formerly put forward by Hickson, Pugh, and Pheysey (1969), further developed by McKelvey (1975) and has been applied amongst the social sciences (i.e., Bunn 1993; Homburg, Jensen, and Krohmer 2008; Moncrief, Marshall, and Lassk 2006). The standard system used to develop empirical taxonomy contains four common steps: The first step identifies the variables to be used to form the categories. Variables are typically derived from several sources. For concepts not clearly specified in the literature, an iterative process of interviews and focus groups are commonly used (Moncrief 1986, Moncrief, Marshall, and Lassk 2006). The second step--measure development--then produces feedback and an empirical foundation on which to specify the variables. In steps three and four, cluster analysis is applied to the data to assemble the objects based on the distinctiveness they possess. The final step "defines the clusters as the categories of the classification scheme--summarizing the similarities and differences across the categories" (Bunn 1993).

Figure 1 shows a five-step procedure for taxonomy development. The principal analytical instrument in taxonomy development is cluster analysis, which assembles "a sample of elements (in survey research, often the respondents) such that the statistical variance should exhibit high internal (with-in cluster) homogeneity and high external (between-cluster) heterogeneity" (Hair et al. 2010). The primary step in cluster analysis is deciding which variables to use with which to group observations (McKelvey 1975).

Therefore, this taxonomy of regulations that affect selling activities/ behaviors starts with the discovery and measurement of applicable sales activities (table 1).

Figure 1

Procedure for the Development of an Empirical Taxonomy



Conceptual Model

To construct the functional taxonomy, we must broadly characterize the subject area by selecting items pertinent to our area of study, for this project, regulations. Therefore, the initial step in creating the proposed regulatory taxonomy of selling activities is to develop a typology of regulations that encapsulate the field of sales and promotion. For this paper, the pharmaceutical industry was selected as the primary area of study. This industry is known for its high level of regulation, including all stages of product life-cycles, including promotion and selling activities. Examples include; sales representatives are prohibited from providing items for healthcare professionals' use that do not advance disease or treatment education, such as; pens, note pads, mugs, and similar "reminder" items with company or product logos (PhRMA 2009). Another example states that companies are prohibited to provide recreational or entertainment events in conjunction with promotional and/or educational meetings with customers (OIG 2006).

The complete typology developed here (Appendix 1) is a conceptually based classification of regulations based on a broad set of federal, state, industry, and firm regulations, thereby ensures that an inclusive list of regulations is incorporated, and reducing the risk of omitting a key regulation. Additionally, only relevant conceptual domains were covered in an effort to keep the number of variables parsimonious. The typology does not attempt to group actual observations, but instead provides the theoretical foundation for the creation of the proposed taxonomy, which will group actual observations.

Toward this end, a two-step selection process was used. First, to identify the conceptual domains and to attain conceptual breadth, websites were reviewed (i.e., aba.com; fda.gov; ftc.gov; oig.hhs.gov; phrma.org), coupled with personal conversations with select industry executives. Second, the core constructs contained within each conceptual domain were selected. Constructs were deemed as core if their relevance was consistently emphasized in the literature, if they were theoretically grounded, and if they applied across companies within the pharmaceutical industry. The two-step collection procedure revealed a total of ninety-four (94) “core” regulations (Appendix 2). The list is comprised of thirty-six OIG, thirty-one PhRMA, nine state, two from the District of Columbia, and sixteen firm regulations (figure 2).

Figure 2
Initial Categories of “Core” Regulations

Source	Number
Office of Inspector General (OIG)	36
Pharmaceutical Research and Manufacturers of America (PhRMA)	31
States	
Massachusetts	2
Maine	1
California	2
Nevada	2
South Dakota	1
Vermont	1

District of Columbia	2
Firms	
Company A	3
Company B	4
Company C	1
Company D	2
Company E	4
Company F	2
TOTAL	94

Conceptual Domains

As appendix 1 indicates, regulations in the pharmaceutical industry are constituted by four conceptual domains. Each domain contains core constructs based on relevance. The order of the domains in appendix 1 does not suggest a hierarchical structure, especially not in the sense that one domain is a functional prerequisite of another; however, they are not completely unrelated. Thus, conceptually, there is an interdependent relationship between domains.

The first conceptual domain is federal regulations. It contains government agencies that are the primary regulators of marketing and sales activities of pharmaceutical firms. The three core primary agency constructs are; (1) The Office of Inspector General (OIG) of the Department of Health and Human Services, which provides compliance procedures for the health care industry. (2) The Federal Trade Commission (FTC), which handle matters affecting consumer protection and competition jurisdiction, and (3) The Division of Drug Marketing and Communication (DDMAC) of the U.S. Food and Drug Administration (FDA), whose mission is “to protect the public health by assuring prescription drug information, is truthful, balanced and accurately communicated.”

The second conceptual domain is state regulations. Currently, six states, and the District of Columbia are identified as having specific regulatory controls that impact selling activities of pharmaceutical companies. They are; Massachusetts, Maine, California, Vermont, South Dakota, Nevada, and the District of Columbia. The remaining forty-five states do not possess individual regulatory controls and only require compliance at the federal level.

The third conceptual domain is industry regulations. The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's foremost pharmaceutical research and biotechnology companies. Their mission is "to conduct effective advocacy for public policies that encourage discovery of important new medicines." To that end, PhRMA "developed and enforces regulations that govern interactions with healthcare professionals that relate to the marketing of products" (PhRMA.org).

The final conceptual domain is firm self-regulations. Pharmaceutical firms have developed and implemented numerous internal controls, procedures, and regulations that promote adherence to requirements of the federal health care program (FDLI 2010). Recognizing that federal guidelines are intended to provide guidance, and often lack the force of law, firms attempt to self-regulate their activities by developing and enforcing numerous internal self-regulations by means of corporate compliance programs. These programs monitor all agents of the sales and marketing function to prevent and detect violations of law or company policy.

As the OIG calls for in its Guidance (OIG 2003), pharmaceutical firms tailor their corporate compliance programs to fit the unique environment of their company, whether it is pharmaceuticals, devices, or diagnostics (Endo 2012; Par 2012; Sanofi 2012). Once companies become aware of possible violations of company policy or law, internal investigations are initiated. Disciplinary action, where appropriate, is taken along with any corrective measures to deter possible future violations.

The Office of Inspector General (OIG) federal guidelines for pharmaceutical manufacturers and The Pharmaceutical Research and Manufacturers of America Code on

Interactions with Healthcare Professionals (PhRMA) are listed in appendix 3. Both the OIG guidelines and PhRMA code regulations are taken directly from their respective published documents. The five states (MA, ME, CA, NV, SD, VT) and the District of Columbia regulations were taken directly from their respective Office of the Attorney General websites (<http://www.atg.state.ma.us>, <http://www.atg.state.me.us>, <http://www.atg.state.ca.us>, <http://www.atg.state.nv.us>, <http://www.atg.state.sd.us>, <http://www.atg.state.vt.us>, and <http://www.dc.gov>) and are listed in appendix 2.

Final Typology of Regulations for this Study

The final typology of regulations was derived by subjecting the entire list of ninety-four “core” regulations to series of content and face validity checks, which produced an inventory of fifty-nine regulations representative of the area being studied. Finally, to check for inter-rater reliability, one regulation that fell outside of the categories of regulations presented was added, for a total of sixty regulations used for this study. The following discussion describes the steps used for constructing the final typology of regulations.

The initial step in developing the regulations taxonomy was to subject the entire list of ninety-four (94) core regulations (OIG, PhRMA, State, and firm) to thorough content analysis, remove replica items and ensure the list only includes unique regulations that were relevant to the area of study and effectively represent the subject area. A panel of eight pharmaceutical industry experts (one Vice President of Sales, two Regional Sales Directors, four Critical Care Sales Representatives, and one Human Resources Manager) was assembled to examine a combined list of thirty-six OIG, thirty-

one PhRMA, nine state, two District of Columbia, and sixteen firm regulations (n=94). They were asked to identify duplicate items, validate only those regulations that applied to the sales function, and unanimously agree on a final list of regulations that accurately reflect their current industry landscape.

This iterative process of specification and comparison by eight pharmaceutical industry experts collectively identified six federal, two industry, nine state, two District of Columbia, and sixteen firm regulations as either extensions or duplicates of existing federal and industry regulations. These thirty-five regulations were therefore combined and eliminated from the finalized list, which included the nine state, two District of Columbia, and sixteen firm regulations, which completely removed the state and firm domains from the final typology. As a result, the final typology of combined regulations contains a complete and parsimonious set of fifty-nine unique regulations described in two domains; federal and industry (Appendix 4). The complete list of regulations used in this study is found in Appendix 5.

Survey Instrument

Once the sales activity list and the inventory of relevant regulations were created, the original survey was formulated to determine the relative significance of each known regulation and its perceived effect on the identified selling activities based on pharmaceutical sales representative perceptions.

Using a seven-point Likert scale (-3 very negatively, -2, -1, 0 not at all, +1, +2, +3 very positively), respondents were asked to individually rate each regulation's effect on their ability to perform the seventeen identified selling activities. A balanced (equal number of positive and negative response choices), bipolar (negative to positive; -3 to +3)

scale was used due to the opposite attributes of the dimensions being studied (Schwarz 1999). Since the notion being measured is not a range with the low end of the scale representing the absence of the attribute, and instead uses two poles describing opposite attributes (“very negatively” and “very positively”), the bipolar numeric properties of the scale were chosen. Furthermore, it appeared logical to use a numbering convention that was in concurrence with the nature of the questions so respondents would not be left to interpret the meaning of the questions (Schwarz et al. 1991). Without providing negative scores, it was anticipated that subjects may interpret an “all positive Likert scale” (1 to 7) as having only a positive impact, and not the presence of negative impact.

Since the questionnaire was developed for the purpose of this study, the instrument was pretested with pharmaceutical sales representatives. Representatives were asked to examine questions for completeness, in other words, the degree to which the list of items effectively encompassed selling activities within the categories of regulations presented. They were also invited to identify any doubt, oversight, or other obscurity when answering each activity item, and also to offer ideas for survey improvement (De Vaus 2002). To test for face and content validity, the preliminary survey containing the complete list of fifty-nine regulations and twenty selling behaviors was appraised by eleven first-line sales managers and twenty-six sales representatives attending their company national sales meeting in the northeastern United States.

In addition, one retired and four current senior level pharmaceutical executives, who were not employees of the sample frame, appraised the survey from the perspective of specificity, readability, accuracy, and internal and external validity. Based on feedback, three sales communication behavior measures (“ability to ask situation

questions”, “used questioning to assess customer needs”, and “ability to ask clarification questions”) were removed since they were deemed duplicative and redundant. Hence, the removal of these three behaviors from the original twenty measures produced a revised total of seventeen items. Finally, to measure inter-rater reliability, one regulation was added to the original fifty-nine that fell outside of the categories of regulations presented; “Speakers and their materials must clearly identify the company that is sponsoring the presentation.” This question was independently coded and used to compare the degree of agreement among raters.

To assess the generalizability of the study, and to establish inclusion criteria for participants, the final survey included queries about respondent job title, position, and qualified experience. A website was used as placement for the survey to facilitate ease of data gathering.

Randomized, Multicenter, Parallel-Arm Clinical Research Trial Design

Given our research objective of empirically developing a taxonomy of sixty identified regulations that accurately reflect their effect on seventeen recognized selling activities, the projected questionnaire would contain 1,020 items. Clearly, the issue of questionnaire length became a major concern. With such an extensive survey, “respondents might not answer properly at later stages of the questionnaire or may stop filling the questionnaire out” due to respondent fatigue and boredom (Berdie 1989). Based on strong conceptual support predating the application of the technique, the primary investigator felt that the number of regulations and the number of selling activities could not be reduced (Hair et al. 2010). Therefore, we propose a method used

by medical researchers (Appel 2006; Localio et al. 2001). "Randomized, multicenter, parallel-arm clinical research data gathering design", as an effective tool to reduce respondent burden without making trade-offs between the amount and quality of information obtained.

Medical researchers commonly use more than one medical center or clinic to gather clinical trial data. This method is known as “multicenter research trial” design. In addition, multiple treatment groups (“arms”) are established to test at least two medications (e.g., treatment A and treatment B). Study participants are randomly assigned one of the respective treatments. This type of study design using “parallel-arms” provides remarkable efficiency by testing multiple treatments in identical populations simultaneously (Appel 2006). The sample size is typically similar across parallel arms such that there is no interaction linking treatments. Hence,

“if there is no interaction between therapies, then one can test the effect of treatment A by combining the results across groups, regardless of whether they receive treatment B. Likewise, one can test the effect of treatment B by combining the results across groups, regardless of whether they receive treatment A” (Appel p.1360).

Due to the large number of required subjects, most large clinical trials are conducted at numerous clinical research centers.

A key requirement when conducting a multicenter, parallel-arm research trial is the establishment of patient or subject “inclusion criteria”. Inclusion criteria are a method of establishing precision in your cohort. In medical research for example, the investigator might suspect that a new brand of hypertension medicine is more effective than an existing brand, but for some reason this seems to be true only for female patients that are over 60 years of age with a history of diabetes and smoking. Based on this

information and the investigator's professional knowledge, he can establish specific inclusion criteria for his study. More specifically, inclusion criteria are the criteria or standards that specify which subjects are to be included in the study leading to increased generalizability. In medical research trials, inclusion criteria may include demographic data, previous medical history, disease states being investigated, and related medical conditions. "Inclusion criteria help identify suitable participants" (Agency for Healthcare Research and Quality AHRQ.gov). It is necessary that these criteria be objective and clearly defined, so that those involved in the study (or investigators trying to duplicate the study) can replicate participant inclusion decisions accurately.

In summary, randomized, multicenter, parallel-arm trials allow clinical investigators to include larger numbers of participants, longer data gathering tools such as surveys, diverse geographic locations, the inclusion of broader population groups, and the ability to compare results among participants, all of which increase the generalizability of the study (Localio et al. 2001). The current study is a randomized, 3-arm parallel group, multicenter study assessing the effect of regulations on selling activities in pharmaceutical sales representatives. It mirrors randomized, multicenter, parallel-arm research trial design methodology with inclusion criteria standards, thereby permitting us to collect responses from three separate arms (surveys), and test and combine a large number of observations (n=7493), regardless of which survey the respondent received (Appel 2006; ACRP 2012). This method is unknown in marketing research and is therefore a new alternative to the heuristic methods that are currently used when massive questionnaires are used.

The Questionnaire

The initial survey instrument contained sixty (60) regulations of which respondents would be asked to rate each of the seventeen (17) selling activities. In order to reduce “respondent burden” and reduce survey length, multicenter, parallel-arm research trial design methodology and inclusion criteria standards were applied which divided the original list of sixty (60) regulations into three separate surveys containing twenty (20) regulations each. A random number generator was used to create a sequence of twenty (20) regulations coupled with the same selling activities in order to develop three respective questionnaires that lack any pattern. Each respondent was asked to rate seventeen (17) identical selling activities based on the impact of the twenty (20) respective regulations listed. In addition, each version contained the same demographic questions, and descriptive variables at the firm level. Exactly twenty (20) regulations, one-third of the complete list, appeared on each of the three versions of the survey; therefore, all respondents did not complete all scales. Each of the three versions of the survey is found in appendix 7.

Sample Frame and Primary Data Collection

Subsequently, the next phase in the process of taxonomy development is to gather data for the purpose of dividing the sample into meaningful groups. As outlined in the conceptual model, primary data collection was from the pharmaceutical industry. Pharmaceutical firms are highly regulated in nearly all stages of the product life-cycle, including promotion and selling activities, which provide an appropriate data source and

sample for this research (Danzon, Keuffel, and rose 2005). Hence, the pharmaceutical industry provides a good context in which to develop and test this model.

In keeping with the multicenter, parallel-arm clinical research trial methodology, a feasibility study was performed. A feasibility study is typically performed as part of the planning process before the initiation of a new clinical study (Hagen et al. 2011). One of the biggest challenges of initiating a new clinical research trial is the identification and recruitment of the appropriate patient population for the study. The feasibility sample frame for this study consisted of phone interviews with company officials from six respective pharmaceutical firms. The interviews were used to ascertain the level of response, company interest, and ability to satisfy a pre-established set of participant inclusion criteria. A subject may be included in the study if all of the following criteria are met:

Inclusion Criteria:

1. *Currently employed by a pharmaceutical firm that is a member of the Pharmaceutical Research and Manufacturers of America Association (PhRMA).*
Since PhRMA regulations are a key aspect of this study, this criterion is necessary for inclusion since not all pharmaceutical companies are members of PhRMA. By requiring participants to be currently employed by a pharmaceutical company that is a member, we ensure that all respondents are subject to the regulations being studied.
2. *Currently works as a salesperson, account representative, managed care representative, or marketing manager.* This criterion was established to ensure all respondents currently work in a capacity that is directly impacted by sales and

marketing regulations. Since our area of study is not appropriate for “jobs” outside of the sales function, this condition safeguards against the inclusion of respondents who would not be suitable participants.

3. *Works in primary care, specialty, hospital, or account management division.*

Pharmaceutical firms typically have numerous “divisions” that target unique customer segments, support different company functions, etc. These four divisions include the majority of sales representatives and the regulations being studied. Therefore, it was important to specify “divisions” that are subjected to the regulations being studied in order to exclude divisions that are not. (For example: contracting, medical affairs, and distribution.)

4. *Successfully completed a training program on “pharmaceutical promotional practices and guidelines”.* This criterion ensures that respondents have a similar level of awareness of the regulations and understands expectations regarding compliance. This standard removes the possibility of a respondent not being previously aware of the regulations being studied.

For construction of the taxonomic system described here, only pharmaceutical salespeople who met all of the above inclusion criteria were used. A sample of 489 pharmaceutical sales representatives was randomly drawn from a large U.S. pharmaceutical firm that employs 1,000 sales professionals. A total of 396 completed surveys were submitted via a website generating an overall response rate of 80.9 percent. After surveys with more than 5 percent of missing data were removed (Little and Rubin 1989; Acuna and Rodriguez 2004), 381 usable surveys were left, producing an effective

response rate of 77.9%. The remaining data from the 381 surveys were used to create the taxonomy. Respondent demographics are reported in the table 2 below.

Table 2
Demographic Profiles of All Respondents, by Individual Survey

	All Respondents	Questionnaire 1	Questionnaire 2	Questionnaire 3
Gender				
Female	189 (49.6%)	63 (51.2%)	65 (51.2%)	61 (46.7%)
Male	192 (50.4%)	60 (48.8%)	62 (48.8%)	70 (53.4%)
Age				
18 to 25 years	90 (23.6%)	28 (22.8%)	26 (20.5%)	36 (27.5%)
26 to 35 years	100 (26.2%)	36 (29.2%)	36 (28.3%)	28 (21.4%)
36 to 45 years	86 (22.6%)	26 (21.1%)	30 (23.6%)	30 (22.9%)
46 and older	105 (27.6%)	33 (26.8%)	35 (27.6%)	37 (28.2%)
Education				
Associates Degree	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Bachelors Degree	159 (41.7%)	54 (43.9%)	54 (42.5%)	51 (38.9%)
Masters Degree	213 (55.9%)	65 (52.8%)	70 (55.1%)	78 (59.5%)
Doctoral Degree	9 (2.4%)	4 (3.3%)	3 (2.4%)	2 (1.5%)
Education Other				
MD	1	0	0	1
ARNP	5	2	2	1
RN	15	5	6	4
LPN	5	1	2	2
Paramedic (PMD)	3	1	1	1
EMT	3	1	1	1
Cath Lab Tech	1	0	0	1
Lab Tech	1	0	0	1
Selling Experience				
Less than 1 year	31 (8.1%)	8 (6.5%)	11 (8.7%)	12 (9.2%)
1 to 5 years	114 (29.9%)	28 (22.8%)	25 (19.6%)	61 (46.6%)
6 to 10 years	86 (22.6%)	23 (18.7%)	35 (27.6%)	28 (21.4%)
11 to 15 years	56 (14.7%)	19 (15.4%)	26 (20.4%)	11 (8.4%)
16 to 20 years	56 (14.7%)	24 (19.5%)	20 (15.7%)	12 (9.2%)
More than 20 years	38 (9.9%)	21 (17.0%)	10 (7.9%)	7 (5.3%)

	All Respondents	Questionnaire 1	Questionnaire 2	Questionnaire 3
Industry Experience				
Less than 1 year	51 (13.4%)	9 (7.3%)	16 (12.6%)	26 (19.8%)
1 to 5 years	114 (29.9%)	34 (27.6%)	33 (25.9%)	47 (35.9%)
6 to 10 years	96 (25.2%)	23 (18.7%)	37 (29.1%)	36 (27.4%)
11 to 15 years	53 (13.9%)	19 (18.7%)	20 (15.7%)	14 (10.7%)
16 to 20 years	47 (12.3%)	23 (18.7%)	17 (13.3%)	7 (5.3%)
More than 20 years	20 (5.2%)	15 (12.2%)	4 (3.1%)	1 (0.7%)
Company Experience				
Less than 1 year	107 (28.1%)	24 (19.5%)	27 (21.3%)	56 (42.7%)
1 to 5 years	123 (32.2%)	45 (36.6%)	38 (29.9%)	40 (30.5%)
6 to 10 years	86 (22.6%)	25 (20.3%)	37 (29.1%)	24 (18.3%)
11 to 15 years	35 (9.2%)	16 (13.0%)	12 (9.4%)	7 (5.3%)
16 to 20 years	28 (7.3%)	11 (8.9%)	13 (10.2%)	4 (3.0%)
More than 20 years	2 (0.5%)	2 (1.6%)	0 (0.0%)	0 (0.0%)
Region				
Northeast	73 (19.2%)	24 (19.5%)	26 (20.5%)	23 (17.5%)
Southeast	99 (25.9%)	32 (26.0%)	33 (25.9%)	34 (26.0%)
Caribbean	7 (1.8%)	3 (2.4%)	3 (2.4%)	1 (0.8%)
Central U.S.	29 (7.6%)	9 (7.3%)	9 (7.1%)	11 (8.4%)
North Central U.S.	64 (16.8%)	18 (14.6%)	19 (15.0%)	27 (20.6%)
Southwestern U.S.	40 (10.4%)	14 (11.3%)	14 (11.0%)	12 (9.2%)
Northwestern U.S.	56 (14.6%)	19 (15.4%)	19 (14.9%)	18 (13.7%)
Nationally (entire U.S.)	13 (3.4%)	4 (3.2%)	4 (3.1%)	5 (3.8%)
College Major				
Marketing	137 (35.9%)	52 (42.3%)	42 (33.1%)	43 (32.8%)
Finance	35 (9.2%)	6 (4.9%)	13 (10.2%)	16 (12.2%)
Accounting	19 (5.0%)	8 (6.5%)	11 (8.7%)	15 (11.4%)
Sales	19 (4.9%)	0 (0.0%)	3 (2.4%)	1 (0.8%)
Education	11 (2.9%)	8 (6.5%)	2 (1.6%)	1 (0.8%)
Psychology	18 (4.7%)	4 (3.2%)	6 (4.7%)	8 (6.1%)
Health Related	90 (23.6%)	24 (19.5%)	31 (24.4%)	35 (26.7%)
Computer Science	4 (1.0%)	2 (1.6%)	2 (1.6%)	0 (0.0%)
Other	48 (12.6%)	19 (15.4%)	17 (13.3%)	12 (9.2%)

CHAPTER 4: DATA ANALYSIS AND FINDINGS

Results

Reflecting the process used by Moncrief, Marshall, and Lassk (2006), the qualitative stage of our data analysis was followed by a two-step quantitative analysis: factor analysis and cluster analysis. Primary groupings of the data were initially identified using factor analysis, followed by cluster analysis to create the actual regulation taxonomy. Other analyses, primarily cross-tabulations, were executed throughout the procedure to help describe and clarify the individual clusters (Moncrief, Marshall, and Lassk 2006).

Using the multicenter, parallel-arm clinical trial data gathering method, aggregating or "stacking" the responses from three individual questionnaires, generated a three-dimensional data set whereby each survey includes approximately one-third of the 7,493 total observations generated by 381 respondents. It was necessary to convert the original three-dimensional data set into a two-dimensional measure in order to accurately factor analyze the overall sample.

This conversion was accomplished by pooling the respondent's ratings for each of the seventeen respective selling activities by individual questionnaire. The pooled data was then calculated into means for the purpose of creating more reliable and valid measures (Gomez-Mejia, Tosi and Hinkin 1987; Zajac 1990). To illustrate the process, one hundred twenty-three respondents rated seventeen selling activities for regulation one, which created a three-dimensional data set. Means were then calculated by averaging each of the one hundred twenty-three responses per individual selling activity to generate a measure for each regulation by selling activity. More specifically, on a 7-

point Likert scale, the average rating of one hundred twenty-three respondents regarding the impact regulation one has on selling activity one is 4.00813. Likewise, using the same scale, the average rating of one hundred twenty-three respondents regarding the impact regulation two has on selling activity one is 4.01626. This methodology was applied to the entire sample of three hundred eighty-one respondents and then, as with the Moncrief (1986) study, the means were used as the clustering basis.

Factor Analysis

To generate meaningful categories (in this study, regulations affecting selling activities), factor analysis using SPSS 17.0 was executed. An unweighted least squares model with an oblique rotation was specified to minimize further bias and allow correlation.

The scree plot (figure 3) indicated a three-factor model. The explained variance by the three factors was 82.6 percent. A score of .4 was used as a cutoff to indicate inclusion in a factor. As shown in table 2, fifteen of the seventeen indicators clearly loaded on one of the three factors. Variables v1, v2, v3, v4, and v16 highly loaded on factor one; variable two is characterized by variables v5, v6, v7, v8, v9, and v10; and factor three has four distinctive characteristics (v11, v12, v13, v14). As shown, v15 and v17 have significant loadings on factors two and one respectively. Since two variables are given on both of these factors, v15 and v17 were deleted from the analysis (Hair et al. 2010). As noted in the table, the factor structure for the remaining fifteen variables is now well defined, representing three distinct groups of variables that are consistent and theoretically supported for the purpose of later cluster analysis.

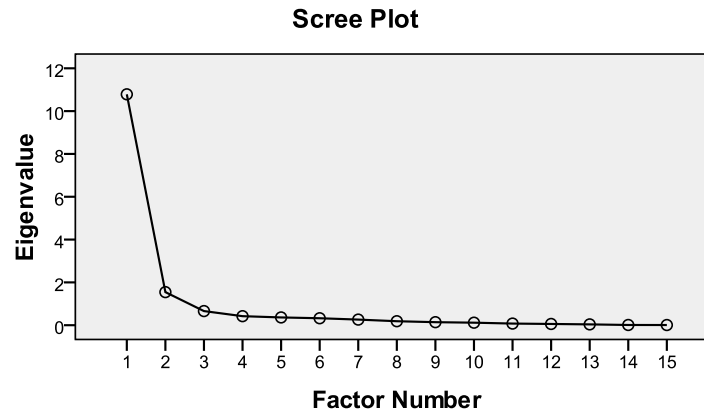
Table 3
Activities Affected by Regulations Factor Analysis

Pattern Matrix Maximum Likelihood Analysis Oblimin Rotation Factor ¹			
	Customer Relationships through Communication	Core Selling Skills	Planning
Indicator			
Ability to ask probing questions (v1)	.934		
Listened to Customer (v2)	.942		
Ability to make a charismatic presentation (v3)	.887		
Ability to work well with others involved in purchase (v4)	.859		
Follow up with customer (v16)	.900		
Gain participation and got customer involved (v5)		.427	
Ability to use analogies and similes in presentation (v6)		.628	
Ability to link product attributes to customer needs (v7)		.565	
Could differentiate product/service from competition (v8)		.587	
Ability to do "homework" on customer (v9)		.592	
Ability to handle objections raised by customer (v10)		.405	
Search out new leads (v11)			.414
Pre-call planning/targeting (v12)			.638
Conduct targeting activities (v13)			.739
Designing sales plan (v14)			.451
Business planning (v15)		.521	.455
Administrative activities/documentation (v17)	.462	.505	

Note. **Bolded** items represent cross-loadings and were therefore eliminated from the analysis

¹Loadings less than .40 are not shown and variables are sorted by highest loading

Figure 3



Description of the Factors

Following the preliminary selling activity groupings, each group was examined and given a name that identifies it by the correlating nature of the selling activities (Hair et al. 2010). The following three selling activity groups emerged from the factor analysis.

Factor 1: “*Customer Relationships through Communication*” (activities x1, x2, x3, x4, x16). The five items that load onto factor 1 relate to activities associated with building relationships with customers through relational communication skills such as asking questions, listening to the customer, ability to make a charismatic presentation, and follow-up with the customer. Thus, this factor was labeled “customer relationships through communication.” Building customer relationships through communication focuses on the “process” of communication (i.e., the how rather than the what), and is maximized by brief social encounters, as well as, longer, ongoing interactions (Grissom, Erchul, and Sheridan 2003).

Factor 2: “*Core Selling Skills*” (activities x5, x6, x7, x8, x9, and x10). Factor 2 involves activities that lead prospects toward the purchase of a product or service by

changing customer perceptions through reason or figurative means. This factor is comprised of six activities that represent foundational selling skills such as linking products to customer needs, differentiating products from the competition, ability to handle customer objections, and the ability to use influential presentation skills to relate to customer needs. Factor 2 was therefore labeled “core selling skills”. Sales people make use of these “core selling skills” as a way to change customer perceptions and influence customer decision making.

Factor 3: “Planning” (activities x11, x12, x13, and x14). Items for factor 3 identified selling activities that help sales people prepare for customer interactions. The act of “planning” for a salesperson is much like “pre-game” activities for sports teams. These are the activities that build a structured understanding that sales people use to become organized, mentally prepared, and solve problems so that everything is “routine” when the sales person is in front of a customer (game-time). Prospecting skills such as searching out new leads, pre-call planning, conducting targeting activities, and designing a sales plan are the selling activities that created Factor 3.

By factor analyzing selling activities from a regulatory impact point of view, we obtained three distinct groups (factors) which generated a novel way to organize selling activities (appendix 8). While the three factor solution reported here generated meaningful categories, it is important to note that the results are specific to the industry studied (pharmaceutical) and represent the interaction between identified regulations and selling activities. As such, our results do not represent generalizability and are subject to empirical validation using other industries with similar regulations.

Cluster Analysis

The objective of the clustering stage was to group different regulations into descriptive classifications. Due to our large data set (7,493 observations) and the need to vary large numbers of clusters, the two-step clustering approach, developed by Chiu et al. (2001) was chosen to develop the taxonomy. “Unlike hierarchical clustering which requires a matrix of distances between all pairs of cases, and the k-means algorithm that requires “shuffling” objects to and from clusters” (Norusis 2008), the SPSS TwoStep Cluster Analysis requires only a single pass of data, and can produce solutions for large data sets for varying numbers of clusters.

Within SPSS 17.0, the two-step cluster method relies on the “auto clustering” procedure when shaping the number of clusters that represents the data sample. The calculation first measures the lowest Schwarz Bayesian Information Criterion (BIC), and then the algorithm adjusts the result by considering solutions with a large “Ratio of Distance Measure”, thus generating the optimal number of clusters. Replication studies have shown that BIC and AIC in combination (Two-Step Cluster) work better than BIC or AIC alone (SPSS 2001). The analysis created six definite clusters which will be described and discussed in the following section.

When performing a two-step cluster analysis within SPSS 17.0, the investigator has the opportunity to supersede the “auto-clustering” default and perform any number of cluster iterations as a cross-validation procedure to corroborate the appropriate number of clusters for the final cluster solution. After five iterations, the procedure was terminated because none of the observations changed membership and the clusters were stable (Bunn 1993).

Moreover, cross-tabulations were performed, crossing each regulation by selling activity, cluster, and a number of demographic variables. The cross-tabulations added value when clarity was needed in interpreting the clusters. Group (cluster) association after this process was the final assignment of the observations to clusters. In the following results section, we list the major factors that play a part in defining each of the six clusters - either positively, negatively, or no role at all.

Classification and Interpretive Description of Clusters:

The two-step cluster analysis produced a six cluster solution, which will be described in this section. The clusters are reported in descending rank order based upon total number of regulations comprised in each respective cluster. For example, Cluster 1 contained the largest number of regulations (19), while Cluster 6 contained the least (4). The following cluster tables contain the specific regulation number assigned for this study, as well as a brief paraphrased description of the actual regulation. The actual regulation descriptions used for this study are provided in the appendix.

Cluster 1: Highly Restrictive Regulations (29.7 Percent of Observations)

Cluster 1: Highly Restrictive Regulations	
Regulation 4 – Manufacturer is prohibited from coupling services that confer a benefit to provider	
Regulation 5 – Sales and marketing functions are prohibited from providing grants	
Regulation 11 – Relationships with customers should not influence decisions for referrals	
Regulation 15 – Compensating physicians for services related to sales and marketing activities are prohibited	
Regulation 16 – Compensating physicians for time spent listening to sales presentations are prohibited	
Regulation 18 – Entertainment, recreation, and travel in association with sales activities are prohibited	
Regulation 19 – Gifts, gratuities, and other business courtesies are prohibited	
Regulation 25 – Meals offered by sales representatives must be limited to in-office or in-hospital settings	
Regulation 26 – Inclusion of a healthcare professional's spouse or guest at a meal is prohibited	
Regulation 28 – Companies are prohibited from providing any entertainment or recreational items	
Regulation 32 – Financial support is prohibited for expenses of non-faculty healthcare professionals	
Regulation 35 – Financial support is prohibited for healthcare professionals for professional meetings	
Regulation 37 – Sponsoring companies are prohibited to influence conference content, venue or faculty	
Regulation 38 – Financial support for the cost of personal expenses at conferences are prohibited	
Regulation 46 – Companies are prohibited from providing recreation or entertainment at meetings	
Regulation 47 – Honoraria and travel expense payments are prohibited at company sponsored meetings	
Regulation 56 – Items intended for personal benefit (such as floral arrangements) is prohibited	
Regulation 57 – Payments in cash or cash equivalents (such as gift certificates) are prohibited	
Regulation 59 – Items designed for education of patients should only be offered on an occasional basis	

Centroids

	Customer Relationships Through Communication		Core Selling Skills		Planning	
	Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation
Cluster 1	-2.81	.278	-2.82	.230	-1.82	.477

The "highly-restrictive regulations" group had the lowest negative scores among the clusters and contains the largest number of regulations from the overall sample. Nineteen of the sixty regulations studied (31.7%) were perceived as highly negative by salespeople in each of the selling activity categories. In this group, regulations impacting a salesperson's ability to perform "core selling skills" scored the lowest (-2.82) among all selling activity categories. "Customer relationships through communication" activities

scored -2.81 followed by "planning" activities at -1.82. This cluster ranks last on each centroid and contains the largest number of observations (n=2224) of the sample.

This finding indicates that the majority of respondents studied perceive a preponderance of regulations as negatively affecting (restricting) their ability to build relationships through communication (relationally communicate), use their core selling skills, and plan.

Cluster 2: No Effect Regulations (27.4 Percent of Observations)

Cluster 2: No Effect Regulations
Regulation 1 – Offer or payment of anything of value for patient referrals are prohibited
Regulation 2 – Remunerative relationships must be identified between company and customers/speakers/consultants
Regulation 3 – Information provided to decision-makers, patients, customers must be accurate and complete
Regulation 7 – Manufacturer must document grant making and educational presentations regularly
Regulation 8 – Any payments to cover the costs of “converting” from a competitor product is prohibited
Regulation 9 – Selective offers of remuneration is prohibited
Regulation 13 – “Switching” arrangements involving cash or other benefits are prohibited
Regulation 14 – Consulting and advisory payments must be at fair market value to bona fide consultants or advisors for their services
Regulation 29 – Giving of any subsidy directly to a healthcare professional by a company is prohibited
Regulation 39 – Consulting agreements are prohibited to serve as either inducements or rewards for prescribing or recommending a particular medicine or course of treatment
Regulation 41 – A legitimate need for the consulting services must be clearly identified in advance
Regulation 43 – The number of healthcare consultants retained must not exceed the number reasonably necessary to achieve the identified purpose
Regulation 50 – Companies must establish policies for the appropriate use of speakers and their training
Regulation 52 – Speaker programs must be monitored for compliance with FDA requirements
Regulation 53 – Healthcare professionals serving as consultants, speakers, or advisors are required to disclose the existence and nature of his/her relationship with the company
Regulation 60 – Grants, scholarships, subsidies, support, gifts, etc are prohibited as exchange for prescribing products or for a commitment to continue prescribing products

Centroids

	Customer Relationships Through Communication		Core Selling Skills		Planning	
	Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation
Cluster 2	-.05	.258	-.07	.315	.10	.388

The "no effect" cluster is the second largest group (n=2052) of observations in the study, representing 27.4% of the sample. Unlike the other five clusters, cluster 2 contains regulations that salespeople perceive having no effect on their selling activities. On a seven-point Likert scale, where -3 indicated "very negatively" and +3 indicated "very positively", this group reported sixteen of the sixty regulations (27.6%) to have little to no effect on selling activities. "Customer relationships through communication" was impacted the least (-.05) followed closely by "core selling skills" (-.07). The final factor, "planning" scored slightly higher (.10), however not high enough to differentiate it from the grouping. In other words, cluster 2 contains regulations viewed as having neutral impact on selling activities.

Cluster 3: Somewhat Restrictive Regulations (16.6 Percent of Observations)

Cluster 3: Somewhat Restrictive Regulations
Regulation 6 – Manufacturer is prohibited from having control over speaker or speaker content
Regulation 10 – Relationships with formulary committee members prohibited to influence decisions
Regulation 21 – Promotional materials must be consistent with approved FDA requirements and cannot be altered, highlighted, etc.
Regulation 31 – The company is prohibited to provide any advice or guidance to CME providers
Regulation 33 – Funding is prohibited to compensate for time spent for participating in CME events
Regulation 42 – Criteria for selecting consultants must be directly related to the identified purpose
Regulation 45 – Venue and circumstances of any meeting with consultants are conducive to consulting services and activities related to purpose of meeting; resorts are not appropriate venues
Regulation 48 – The selection or retention of speakers must be based on defined criteria

Centroids

	Customer Relationships Through Communication		Core Selling Skills		Planning	
	Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation
Cluster 3	-1.55	.646	-2.26	.443	-1.08	.527

This group ranked third in overall negative impact (16.6%) with 1241 overall observations. Of the three centroids, "core selling skills" had the lowest negative score (-2.26) ranking it the fourth most negative category among all groups. "Customer relationships through communication" and "planning" scored slightly better, however they were all perceived as negative. Cluster 3 is still relatively low on all measures and contains eight of the sixty regulations (13%) studied. This group was most similar to cluster 2 with respect to overall negative impact.

Cluster 4: Restrictive in Office Regulations (11.2 Percent of Observations)

Cluster 4: Restrictive in Office Regulations
Regulation 12 – Good or services provided to eliminate an expense that the physician would have otherwise incurred is prohibited
Regulation 17 – Payments for time spent accessing web sites to view or listen to marketing information or to perform research is prohibited
Regulation 27 – Offering “take-out” meals or meals to be eaten without a company representative present is prohibited
Regulation 44 –The retaining company must maintain records for consulting services provided
Regulation 49 – Companies are required to “cap” the total amount of speaker compensation it will pay annually
Regulation 55 – Promotional items such as; pens, note pads, mugs and similar “reminder” items with company logos or product names are prohibited
Regulation 58 – Items designed for education of patients must be \$100 or less in value

Centroids

	Customer Relationships Through Communication		Core Selling Skills		Planning	
	Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation
Cluster 4	-.97	.558	-.59	.527	-1.55	.494

This category contains two factors that were slightly negative, and equally revealed minimal factor centroid values and rankings; "core selling skills" (-.59) and "customer relationships through communication" (-.97). "Planning", the third factor, reported a much more negative score (-1.55) indicating that activities such as searching out new leads, pre-call planning, conducting targeting activities, and designing sales plans were more negatively impacted by this group of regulations.

Cluster 5: Bad with Customer / Good in Office (8.5 Percent of Observations)

Cluster 5: Bad With Customer / Good In Office Regulations
Regulation 23 – Occasional meals may be offered, so long as the presentation provides scientific value
Regulation 30 – Financial support must be given to the CME provider directly
Regulation 34 – It is prohibited to provide meals directly at CME events, except that the CME provider may apply the financial support from the company to provide meals for all participants
Regulation 36 – Financial support for conference registration fees must be given directly to the conference sponsor and not to participants
Regulation 54 – Financial assistance for scholarships or other educational funds to support medical students, residents, or fellows may not be offered directly, but may be offered to the institution

Centroids

	Customer Relationships Through Communication		Core Selling Skills		Planning	
	Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation
Cluster 5	-2.29	.387	-1.81	.373	1.14	.402

Examination of the fifth group (636 observations) shows that “customer relationships through communication” and “core selling skills” were both negative (-2.29 and -1.81 respectively). “Planning” on the other hand was positive at 1.14. Cluster 5 is unique compared to the other clusters such that no other clusters reported a mix between positive and negative means across centroids.

Cluster 6: Helpful Regulations (6.7 Percent of Observations)

Cluster 6: Helpful Regulations
Regulation 20 - Promotional material claims must be fair and balanced
Regulation 22 - Meals may be offered to customers and staff as long as they are modest in value
Regulation 24 – Occasional meals must be accompanied by educational or scientific presentations
Regulation 40 – Written contracts must specify the nature of consulting services to be provided

Centroids

	Customer Relationships Through Communication		Core Selling Skills		Planning	
	Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation
Cluster 6	2.55	.500	2.39	.711	2.54	.439

This group scored the highest with respect to regulations that are perceived by salespeople as "helpful" when performing selling activities. On a scale of -3 to +3, this group had the highest mean score on "customer relationships through communication" (2.55), "core selling skills" (2.39), and "planning" (2.54). This category of regulations includes the approval of activities such as providing meals to customers and staff, the initiation of contracts with customers to enforce agreed upon services, and requirements of firms to substantiate product claims. Each of these regulations was perceived by salespeople to facilitate communication with prospects, assist their interpersonal influencing efforts, and support planning efforts. Thus, this cluster was labeled "helpful" indicating that the majority of sales people perceived regulations 20, 22, 24, and 40 as useful. "Helpful Regulations" is the smallest cluster representing just 6.7% of 7493 total observations. Four of the sixty regulations included in this study reside in cluster six. This finding indicates that less than 7 percent of the regulations examined are perceived as "helpful" by salespeople.

CHAPTER 5: CONCLUSION, LIMITATIONS, AND FUTURE RESEARCH

Discussion

The results of this study offer a classification system based on three selling activity factors and six clusters or groups of regulations. Table 3 gives the mean ratings for each taxonomic group across group descriptors. The discussion provided in the following section is based on the results supplied by this table.

Table 3

Centroids

		Customer Relationships Through Communication		Core Selling Skills		Planning	
		Mean	Std. Deviation	Mean	Std. Deviation	Mean	Std. Deviation
Cluster	1	-2.81	.278	-2.82	.230	-1.82	.477
	2	-.05	.258	-.07	.315	.10	.388
	3	-1.55	.646	-2.26	.443	-1.08	.527
	4	-.97	.558	-.59	.527	-1.55	.494
	5	-2.29	.387	-1.81	.373	1.14	.402
	6	2.55	.500	2.39	.711	2.54	.439
	Combined	-1.24	1.539	-1.29	1.545	-.60	1.357

The results are interesting and instructive for a number of reasons. First, six clusters of regulations were revealed which provide a foundation for understanding the interaction between regulations and selling activities in the form of an empirical taxonomy. This study revealed that salespeople perceive most regulations as either highly restrictive (cluster 1), or have no effect at all (cluster 2) on their selling activities. Very few regulations (only four out of sixty) were perceived as helpful.

“Highly Restrictive” Regulations (cluster 1)

Respondents perceived the first cluster as the most restrictive and highly negative group of regulations when doing their job as a salesperson. This cluster also represents the largest number of regulations in one group (n=19), indicating an overall perception that most regulations are viewed as highly restrictive by salespeople. A thorough examination of the regulations within the “highly restrictive” group reveals numerous specific examples that limit time with customers, prohibit gifts and entertainment, and other business courtesies. This suggests that the majority of regulations enforced by the OIG, and PhRMA may prevent customer relationship opportunities, which by default restrict a salesperson’s ability to execute core selling skills and planning.

“No Effect Regulations” (cluster 2)

The “no effect” cluster is the second largest group containing sixteen regulations (n=16). Examination of specific regulations linked with “no effect” show that regulations designed to control firm level behavior, enforce federal and state laws such as anti-kickback legislation, and regulations governing forms of remuneration were not perceived by salespeople as positive or negative with respect to their ability to perform selling activities. Many of the regulations within this group are directed more toward the firm level and show neutral or no effect on selling activities by sales representatives. This is an interesting finding in two respects. First, this suggests that a large portion of regulations may not be necessary considering they are viewed to have no impact on selling activities. Second, as federal, state and local agencies continue to generate more

regulations targeted toward sales forces, and with over 27% of existing regulations having no effect on selling activities, a thorough needs analysis should be conducted prior to implementation of the regulation.

“Somewhat Restrictive Regulations” (cluster 3)

Cluster three is unique such that the eight regulations (n=8) comprising this group are largely related to third party entities which limits or eliminates the ability of a salesperson to interact directly with their customers. For example, regulation 10 specifically states that “relationships with formulary committee members should not include any remuneration from a manufacturer or its agents, nor to influence formulary decisions...” In its most basic form, a “formulary” is a list of medicines that specify which products are approved or available for physicians to prescribe. The formulary committee is a group of advisors comprised primarily of staff physicians and pharmacists which ultimately determine what products are placed on “formulary” (ASHP 2009). Therefore, it is not surprising that sales representatives view these regulations as “highly-restrictive” since they prohibit key selling activities that can influence customer buying decisions.

In addition, many pharmaceutical firms use third-party vendors to conduct promotional speaking events, educational symposia, and physician speaker events. However, rules like regulation number six specifically state; “the manufacturer should have no control over the speaker or content of an educational presentation.” This form of regulation prohibits the sales person from speaking directly with a customer who they have sponsored to speak. All content must go through a third-party entity. Thus, the

salesperson is unable to build customer relationships, use his/her core selling skills, and plan. This finding indicates that salespeople perceive certain regulations as somewhat restrictive when dealing with entities other than their direct prospects.

“Restrictive in Office Regulations” (cluster 4)

Overall, the regulations grouped in the “restrictive in office” cluster (n=7) are all perceived to have a negative impact on selling activities. However, unlike the “no effect” cluster which was highly negative in all categories, this cluster was slightly negative in customer relationships through communication, and core selling skills. On the other hand, planning was ranked highly negative in this category. Inspection of the seven regulations linked with the “restrictive in office” cluster suggests that planning activities are perhaps more strategic and therefore experience a greater negative impact than other more direct customer activities such as relationship building and core selling skills.

Historically, giving inexpensive “reminder” promotional items (pens, note pads, mugs, etc. with company logos or product names) to potential and existing customers was a common selling activity for pharmaceutical representatives. This practice was believed to enhance a sales person’s ability to “gain access” to new customers, search out new leads, and conduct targeting activities. For example, experienced sales people would use a coffee mug that contained their product name and logo as a way to get a customer’s attention and to initiate product or service discussions.

Regulation 55, cluster 4, currently prohibits the practice of *providing items for healthcare professionals’ use that do not advance disease or treatment education*, consequently the salesperson perceives this regulation as “highly restrictive” when

conducting planning activities such as pre-call planning, and searching out new leads. However, it was perceived to have minimal negative effect on activities such as listening to customers or handling customer objections. This discovery demonstrates the different effects a regulation can have depending on the specific selling activity being conducted.

“Bad with Customer / Good in Office Regulations” (cluster 5)

The “bad with customer / good in office” cluster (n=5) produced a unique distinction suggesting this group of regulations has an opposite effect on selling activities conducted in front of customers ("customer relationships through communication" and "core selling skills", -2.29 and -1.81 respectively) versus those conducted away from customers (“planning”, 1.14). Inspection of the five regulations in the “bad with customer / good in office” cluster reveals that four of the regulations (regulations 30, 34, 36, and 54) limit and/or prohibit providing meals, financial support, or other business courtesies unless it is facilitated through a third-party entity such as conference sponsors, event planners, or academic or training institutions. In addition, regulation 23 states; “occasional meals may be offered as a business courtesy to healthcare professionals (including members of their staff) attending sales/marketing presentations *as long as* the presentations provide scientific or educational value”.

Each of the regulations in “bad with customer / good in office” contain a “condition” statement (i.e., as long as; only if; or except that) that appears to separate selling activities conducted in the customer’s presence (“customer relationships through communication" and "core selling skills") from those conducted away from customers (“planning”). The existence of the “condition” statements appear to have opposite effects

on selling activities that are conducted while face-to-face with customers versus those conducted outside the presence of a customer. This finding, the fact that certain regulations can have both positive and negative effects on selling activities, further supports the value of a classification system such as the taxonomy presented here.

“Helpful Regulations” (cluster 6)

After examining the four regulations (n=4) found within the “helpful” group, we observed that each of the regulations supported activities such as providing customers with occasional meals, the ability to include staff members in the activity, and the requirement that customers must sign a contract describing the nature of their commitment and services to be provided. If a regulation makes it easy to gain access to a customer, and facilitates relationship building such as providing a meal, it is not surprising that sales representatives would find these regulations as “helpful”. What this suggests is that sales organizations may benefit by providing their salespeople with regulations describing what they "can" do rather than what they "cannot" do. Each of the four regulations within this group specifically states examples of promotional activities that are allowed. Of note, these are the only four regulations that describe what is allowed versus what is prohibited. The usefulness of these regulations was viewed as positive by all respondents indicating a wide acceptance among the entire sales force.

Taxonomy in Research

This article defines the process and reports the findings of a comprehensive taxonomy development effort, based on how regulations affect selling activities. The

basis of the entire project, however, is that sales forces continue to spend billions of dollars annually to support thousands of direct salespeople and their activities, without any understanding of the interrelated phenomena that regulations impose on selling activities. Clearly, the growing number of regulations placed upon sales forces indicates a critical transformation in the business setting that affects the discipline of selling and sales management. Taxonomies are consistently used in business research and are fundamental in classifying and learning about phenomena. Until now, conceptualization of how regulations affect selling activities has not been empirically studied. The results of this study and the taxonomy presented here offer numerous insights into organizing complex sets of regulations and selling activities.

The taxonomy produced in this study is based on three (3) factors and six (6) clusters or groups. Of particular interest, the results of the factor analysis revealed three distinct groups of selling activities; (1) customer relationships through communication, (2) core selling skills, and (3) planning. They seemingly resemble the sales communication behaviors measures (“get”, “give”, and “use”) adapted from Reid, Minton, and Plank (1996), however by examining the selling activities in the presence of regulations, our factor analysis effectually combined “questioning”, “listening”, “charismatic presentations”, and “working well with people” into its own category renamed “customer relationships through communication”. The second new group (factor) that was identified includes a combination of “customer participation”, “getting customers to see product benefits”, “meeting customer needs”, and “ability to handle objections”. This new category represents “core selling skills” that engage customers in the buying process. Finally, the last category (“planning”) grouped items that involved

activities conducted away from customers such as “pre-call planning”, “designing a sales plan”, and “conducting targeting activities”. From a selling perspective, it is quite interesting to learn that the presence of regulations changed the sales communication behavior categories into different groupings effectually describing new categories of selling activities.

The taxonomy of regulations presented herein provides a fascinating picture of the impact they can have on selling activities. Although much has been written about the existence of regulations in business, our study is the first to specifically investigate and supply strong support through an empirically derived taxonomy how certain regulations affect some selling activities more than others. One of our key findings indicates that the perceived effects of regulations are very “cleanly” loaded into respective categories (clusters) by respondents. In other words, there is a very high degree of homogeneity within clusters. For example, regulations that prohibit gift giving, entertainment, business courtesies, and other relationship building activities loaded exclusively into the “highly restrictive” (very negative) cluster of regulations by all respondents with no respondent ratings found in other clusters. The same high degree of homogeneity was observed in the “helpful” (very positive) cluster of regulations whereby all respondents perceived the ability to “provide meals to customers”, “provide meals to staff”, and “written contracts with customers” as positively affecting their ability to do their job as a sales person. This finding suggests that pharmaceutical representatives are very clear and consistent regarding how regulations affect their selling activities. This could be a reflection of the level of regulatory training they receive or possibly the clear explicit nature of how the regulations are written, obviously a fertile area for future research.

By using these categories, future researchers can add generalizability to their findings on the impact of regulations allowing comparisons across industries, regulating entities, and regulations themselves. It is hoped that the tool created here will spur research into the interaction between regulation and sales.

Managerial Implications

In terms of practical application, the taxonomy developed in this study could help a manager develop their own companies' approach to regulations and ascertain the impact different regulations have on their sales force activities. Furthermore, the value in our taxonomy lies in its potential to provide managerial insight and direction by isolating groups of regulations with predictive significance regardless of industry.

Sales managers whose industries are exploring the idea of tighter regulatory controls, or whose firms have not considered the impact regulations might have on their sales and marketing activities, can use this taxonomy to develop alternative selling strategies to enhance customer impact. For example, by identifying whether salespeople perceive a regulation as "highly restrictive", "helpful", or having "no effect" on their day-to-day activities, a manager can tailor training and education for his/her sales force in order to provide the skills necessary to better serve their customers as well as comply with the regulation(s).

From a marketing perspective, using the known clusters of regulations, practitioners can verify whether the promotional materials and activities they believe are vital to their sales team fit into one of the six clusters, or not. Based on the cluster, marketing managers should consider whether or not they want to produce particular

resources and supplies, or develop different strategies to accommodate the growing number of regulations with which they must comply. In other words, are there certain strategies that allow them to overcome issues related to regulations and their selling activities better than others?

For the sales manager, this study may be useful in the identification of skills and behaviors associated with highly effective sales representatives in a highly regulated environment. For example, a successful pharmaceutical representative that relies heavily on building customer relationships through communication as their primary selling skill may find the regulation that *permits occasional meals at meetings, so long as the presentation provides scientific value*, as highly restrictive. From their perspective, they prefer to have lunch with a customer to build relationships and rapport and believe that conducting a scientific presentation would negatively impact their interaction. Therefore, they may decide to not provide occasional meals at all and exclude customers that will only meet over lunch. On the other hand, another successful pharmaceutical representative has found that conducting scientific presentations at lunch meetings is an effective way to search out new leads, target customers, and design their sales plan. For those reasons, the second representative routinely meets new customers over lunch meetings while sharing scientific product information. This example implies the need for further training among affected sales representatives and managers based upon identified best practices.

Finally, from the taxonomy developed in this study, managers can sort their own companies' regulations on the basis of the classification scheme presented. From the

taxonomy, they can determine new ways to approach customers and develop alternative selling strategies.

Limitations and Future Research Opportunities

Before future research opportunities are noted, several limitations should be raised. First, the sample in this study included sales representatives from one firm within the pharmaceutical industry. Although pharmaceuticals is known to be one of the most regulated industries today, industries such as banking, real estate, telecommunications, and tobacco would also be appealing and meaningful for other investigators to test our taxonomical methodology. We acknowledge this as a "limitation", however this was a mindful strategic choice in designing the research.

An inherent limitation of the taxonomic process includes several subjective and sequential decisions related to data analysis. We recognize that strong conceptual support is necessary to deal with issues such as what variables to include, why groups exist in the first place, and determining the number of clusters in the final solution. Additionally, analysis of this type of data required several different analytical approaches; however the present study relies heavily on the use of exploratory factor analysis (EFA), and two-step cluster analysis. Though each step of the analysis was carefully specified and reviewed by two additional researchers, applying a different sequence of analytical steps might deduce the data in a slightly different way. We recognize that problems are inherent in both methods which is acknowledged.

Future research directions are several. Marketing and sales scholars can play an important role in the growing area of regulations and selling. To date, key decisions

about how to effectively sell in an ever increasing regulated environment have been guided by “reaction” and “intuition” rather than by marketing/sales experts and scholars. Research in the area of sales strategy development is needed to guide these decisions which often have huge financial consequences. Building upon an initial taxonomical scheme, as described here, can help develop theoretical strategy frameworks for future research in the areas of relational communication, and interpersonal influencing in the context of selling. Moreover, further research could explore which regulations impact customer commitment and trust (Morgan and Hunt 1994).

There is a pressing need for better understanding of the costs associated with regulations placed on sales organizations. Many companies are unaware of the costs to monitor, enforce, and implement regulations within their organizations and how those costs impact overall firm performance. It would be interesting to extend this regulatory taxonomy to include demographic data, longitudinal performance outcomes, and cost measures. With large quantities of complex and vague regulations with which sales people must comply, our research underscores the need to execute fiscal analyses on the major clusters of regulations to examine whether a regulation’s intended benefits surpass its costs. The research presented here provide a timely context for further research on the interaction between regulations and selling behaviors, which seem to be central to the advancement in research selling and sales management.

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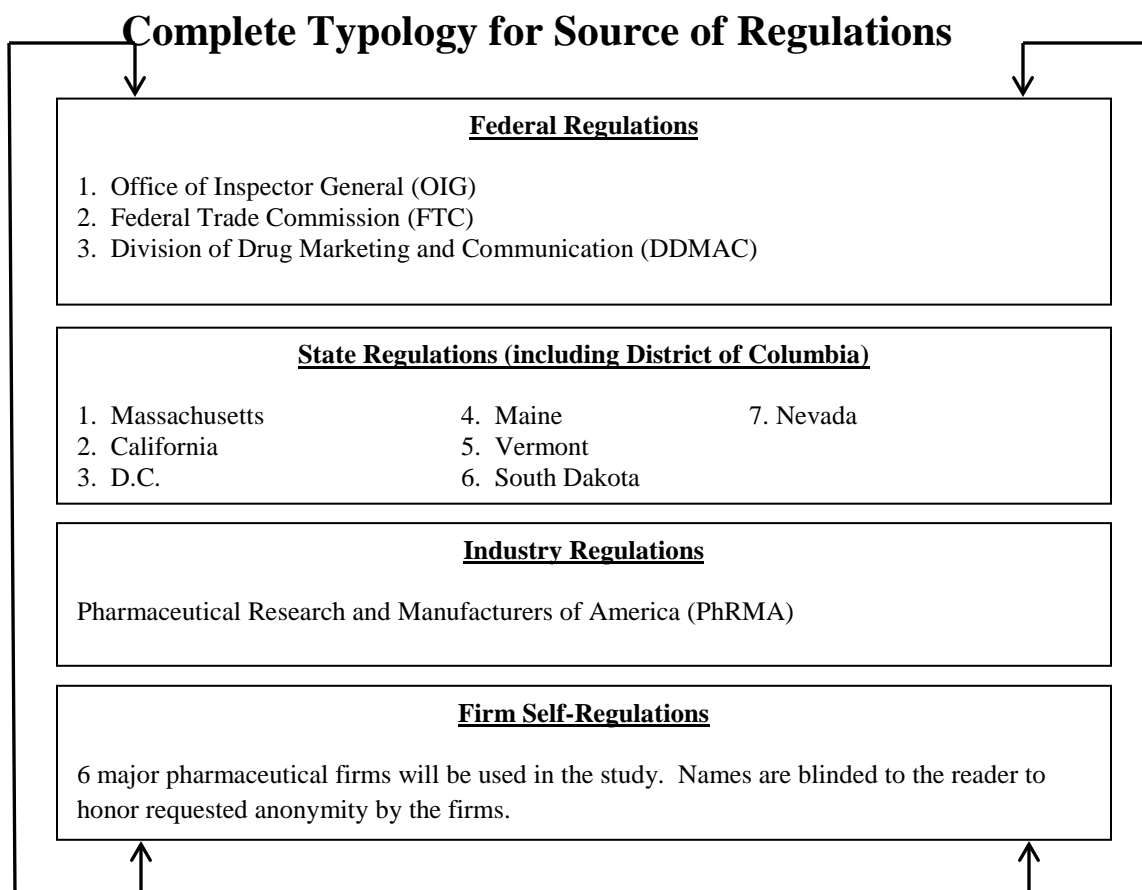
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APPENDIX 1

APPENDIX 2

Comprehensive list of the 94 “core” regulations

ID	Guideline / Regulation
1	Pharmaceutical manufacturers must develop and distribute written standards of conduct, as well as written policies, procedures and protocols that verbalize the company’s commitment to compliance.
2	Pharmaceutical manufacturers must include adherence to the compliance program as an element in evaluating management and employees.
3	Pharmaceutical manufacturers must address specific areas of potential fraud and abuse, such as the reporting of pricing and rebate information to the federal health care programs, and sales and marketing practices, within their policies and procedures.
4	Pharmaceutical manufacturers must designate a compliance officer other appropriate bodies (e.g., a corporate compliance committee) charged with the responsibility for developing, operating, and monitoring the compliance program, and with authority to report directly to the board of directors and/or the president or CEO.
5	Pharmaceutical manufacturers must develop and implement regular, effective education and training programs for all affected employees.
6	Pharmaceutical manufacturers must create and maintain an effective line of communication between the compliance officer and all employees.
7	Pharmaceutical manufacturers must develop a process (such as a hotline or other reporting system) to receive complaints or questions.
8	Pharmaceutical manufacturers must adopt procedures to protect the anonymity of complaints and to protect “whistleblowers” from retaliation.
9	Pharmaceutical manufacturers must use audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems.

10	Pharmaceutical manufacturers must develop policies and procedures for addressing the non-employment or retention of individuals or entities excluded from participation in federal health care programs.
11	Pharmaceutical manufacturers must enforce appropriate disciplinary action against employees or contractors who have violated company policies and procedures and/or applicable federal health care program requirements.
12	Pharmaceutical manufacturers must develop policies and procedures for the investigation of identified instances of noncompliance or misconduct.
13	Policies and procedures for the investigation of identified instances of noncompliance or misconduct must include directions regarding the prompt and proper response to detected offenses, such as the initiation of appropriate corrective action and preventive measures and processes to report the offense to relevant authorities in appropriate circumstances.
14	Every pharmaceutical manufacturer is required to develop and distribute written compliance standards, procedures, and practices that guide the company and the conduct of its employees in day-to-day operations.
15	Policies and procedures that guide the company and the conduct of its employees in day-to-day operations must be developed under the direction and supervision of the compliance officer, the compliance committee, and operational managers.
16	At a minimum, the policies and procedures must be provided to all employees who are affected by these policies, and to any agents or contractors who may furnish services that impact federal health care programs (e.g., contractors involved in the co-promotion of a manufacturer's products).
17	Pharmaceutical manufacturers must develop a general corporate statement of ethical and compliance principles that will guide the company's operations.
18	Pharmaceutical manufacturers must develop of code of conduct statement of principles to include the company's expectations of commitment to compliance by management, employees, and agents, and should summarize broad ethical and legal principles under which the company must operate.
19	Pharmaceutical manufacturers must include their board of directors, CEO, president, members of senior management, and other personnel from various levels of the organizational structure in the development of all aspects of

	the compliance program, especially the code of conduct.
20	Pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes.
21	Pharmaceutical manufacturers are prohibited to offer payments (in any form, whether the payments are direct or indirect) purposefully to induce or reward the referral or generation of federal health care business. (Anti-kickback statute)
22	Pharmaceutical manufacturers are prohibited to offer anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a federal health care program.
23	Pharmaceutical manufacturers are prohibited to solicit or accept remuneration for referrals.
24	Pharmaceutical manufacturers must identify any remunerative relationship between itself (or its representatives) and persons or entities in a position to generate federal health care business for the manufacturer directly or indirectly.
25	Pharmaceutical manufacturers are prohibited from arrangements or practices that have a potential to interfere with, or skew, clinical decision-making.
26	Pharmaceutical manufacturers are prohibited from arrangements or practices that have a potential to undermine the clinical integrity of a formulary process.
27	Pharmaceutical manufacturers are prohibited from arrangements or practices that involve providing information to decision-makers, prescribers, or patients that does not include complete and accurate information (not misleading).
28	Pharmaceutical manufacturers are prohibited from arrangements or practices that have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees.
29	Pharmaceutical manufacturers are prohibited from arrangements or practices that have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation.
30	Pharmaceutical manufacturers are prohibited from arrangements or practices that have a potential to increase the risk of overutilization or inappropriate utilization.
31	Pharmaceutical manufacturers are prohibited from arrangements or practices that raise patient safety or quality of care concerns.
32	Pharmaceutical manufacturers are prohibited from

	providing any remuneration to a direct purchaser (e.g., hospitals, nursing homes, pharmacies, some physicians), as well as indirect purchasers (e.g., health plans) that is expressly or impliedly related to a sale.
33	Pharmaceutical manufacturers are prohibited from hiding de facto pricing concessions to other purchasers to avoid passing on the same discount to others.
34	Pharmaceutical manufacturers are prohibited from offering services that have no substantial independent value to the purchaser (e.g., billing assistance tailored to the purchase products, reimbursement consultation, and other programs specifically tied to support of the purchased product).
35	Pharmaceutical manufacturers are prohibited from offering funding (grants) that are conditioned, in whole or in part, on the purchase of products.
36	Pharmaceutical manufacturers are prohibited from influencing the substance of an educational program or the presenter.
37	Pharmaceutical manufacturers must separate their grant making functions from their sales and marketing functions.
38	Third-party scientific and educational conferences or professional meetings are permitted provided; (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse, (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.
39	The pharmaceutical manufacturer should have no control over the speaker or content of any educational presentation.
40	Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) are prohibited.
41	Payments in cash or cash equivalents (such as gift certificates) are prohibited.
42	Pharmaceutical manufacturers are prohibited from offering payments to cover the costs of “converting” from a competitor’s product.
43	Pharmaceutical manufacturers are prohibited from providing selective offers of remuneration (i.e., offers made to some but not all purchasers).
44	Pharmaceutical manufacturers are prohibited from offering any remuneration directly or indirectly to person(s) in a position to influence formulary decisions related to the manufacturer’s products.
45	Pharmaceutical manufacturers are prohibited from offering

	lump sum payments for inclusion in a formulary or for exclusive or restricted formulary status.
46	Pharmaceutical manufacturers are prohibited from providing anything of value to a physician who might prescribe the manufacturer's product.
47	Pharmaceutical manufacturers are prohibited from providing switching arrangements that involve offering physicians cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product.
48	Pharmaceutical manufacturers are prohibited from compensating physicians as "consultants" when they are expected to attend meetings or conferences primarily in a passive capacity.
49	Pharmaceutical manufacturers are prohibited from compensating physicians for services connected directly or indirectly to a manufacturer's marketing and sales activities, such as speaking, certain research, or preceptor or "shadowing" services.
50	Providing items for healthcare professional' use that do not advance disease or treatment education, even if they are practice-related items of minimal value (such as pens, note pads, mugs and similar "reminder" items with company or product logos) are prohibited.
51	Pharmaceutical manufacturers are prohibited from compensating physicians for time spent listening to sales representatives market pharmaceutical products.
52	Pharmaceutical manufacturers are prohibited from compensating physicians for time spent accessing web sites to view or listen to marketing information or perform "research".
53	Pharmaceutical manufacturers are prohibited from providing entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations.
54	Pharmaceutical manufacturers are prohibited from offering gifts, gratuities, and other business courtesies.
55	Pharmaceutical manufacturers and their representatives are prohibited from using activities that channel improper remuneration to physicians or others in position to generate business for the manufacturer or to influence or control the content of a program.
56	Modest, occasional meals are permitted as long as they are offered in the appropriate circumstances and venues.
57	Companies are required to separate its CME grant-making functions from its sales and marketing departments.

58	Pharmaceutical manufacturers are required to institute and implement corrective action and disciplinary policies applicable to sales agents who engage in improper marketing.
59	Pharmaceutical manufacturers are required to avail itself of the advisory opinion process if it has questions about particular practices used by its sales force.
60	Pharmaceutical manufacturers are required to establish an effective system for tracking, compiling, and reviewing information about sales force activities, including if appropriate, random spot checking.
61	Pharmaceutical manufacturers are required to provide accurate and not misleading promotional materials when interacting with healthcare professionals.
62	Promotional materials provided to healthcare professionals must only make claims about a product when properly substantiated.
63	Promotional materials provided to healthcare professionals must reflect the balance between risks and benefits.
64	Companies are prohibited from providing meals directly at CME events, except that a CME provider at its own discretion may apply the financial support provided by a company for a CME event to provide meals for all participants.
65	Any meals offered in connection with informational presentations made by field sales representatives or their immediate managers should also be limited to in-office or in-hospital settings.
66	Inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is prohibited.
67	It is prohibited for companies or agents of the companies to provide entertainment or recreational items, such as tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any healthcare professional who is not a salaried employee of the company.
68	It is required that companies adopt a Comprehensive Compliance Program (CCP) that is in accordance with both the OIG Guidance and the most recent version of the PhRMA Code.
69	Pharmaceutical companies are required to annually set a spend limit on gifts and meals to California HCPs and publicly post that limit, along with a copy of its CCP and certification of compliance.
70	Manufacturers and wholesalers who employ a person to

	sell or market a drug, medicine, chemical, device or appliance in the state must file annual submissions with the Nevada Board of Pharmacy confirming compliance with the law's training, investigation and auditing requirements.
71	The law requires manufacturers and wholesalers to adopt a Marketing Code of Conduct setting forth the company's "practices and standards that govern the marketing and sale of its products.
72	Companies are required to disclose the value, nature and purpose of gifts provided to HCPs
73	Requires companies to adopt and certify compliance with the Massachusetts Department of Health's Marketing Code of Conduct provisions.
74	limits the ability of PBMs to switch South Dakota residents' prescription drugs by allowing higher-priced drugs to be substituted for lower-priced prescribed drugs only for medical reasons that benefit the covered individual
75	Sales representatives are required to obtain a license to "practice pharmaceutical detailing" in the District while certifying compliance with a marketing code of ethics.
76	Sales representatives who interact with District of Columbia HCPs must keep detailed records about those interactions. These records include not only the contact information for the HCP or the employee or representative of the HCP, but also details about the types of promotional materials left with the individual and whether any sample products were provided.
77	Reporting of expenses related to company-sponsored educational and informational sessions, including food, entertainment, travel, gifts valued at \$25 or more.
78	The provision of gifts by pharmaceutical and medical device manufacturers to healthcare professionals is prohibited.
79	All sales and marketing employees are required to successfully pass the company developed pharmaceutical promotional guidelines exam.
80	All sales and marketing employees are prohibited to participate in customer meetings when a scientific manager (liaison) is present.
81	Sales representatives must receive prior approval from their immediate supervisor for all promotional expenditures.
82	It is prohibited for sales representatives to "steer" physician speaker content or presentation materials.
83	All speaker events are prohibited.
84	Providing entertainment, meals, and gifts is prohibited by all sales and marketing personnel.
85	Sales representatives are prohibited from attending

	scientific/educational meetings conducted by medical affairs or scientific liaisons.
86	Sales representatives are prohibited from altering promotional materials in any way (e.g., using yellow highlighters, circling certain items of interest, etc.).
87	Sales representatives are prohibited to use any “non-approved” promotional information items (e.g., books, newspaper articles, articles printed from the web, etc.)
88	Sales representatives must provide an approved promotional proof source at every customer interaction.
89	Sales representatives are prohibited from offering “take-out” meals to customers.
90	Sales representatives are prohibited from responding to customer questions not related to their own product (e.g., competitive product questions).
91	Sales representatives are prohibited to discuss non-approved (FDA) indications for their products. Even if asked by the physician.
92	Sales representatives are prohibited from using competitive product package inserts to make product comparisons.
93	If a sales representative is a currently licensed medical professional (e.g., R.N., Paramedic, M.D., etc.) it is prohibited to exercise the skills by which you are licensed while actively working for the company. In other words, it is prohibited to offer medical advice, care, etc. while working as a representative of the company.
94	Sales representatives are prohibited from participating in “preceptorships” or “shadowing” events with physicians or other medical professionals.

APPENDIX 3

REGULATIONS:

OFFICE OF INSPECTOR GENERAL (OIG), HHS;

**THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF
AMERICA (PhRMA)**

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency: Office of Inspector General (OIG), HHS

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

Background

Preventing and reducing fraud and abuse in federal health care programs is a major initiative of the OIG (Federal Register 2003). The OIG states (2003, p. 23731), “The purpose of the compliance program guidance is to encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements.”

Guidelines/ regulations for pharmaceutical manufacturers:

- A. Title: The Basic Compliance Elements
 - a. The development and distribution of written standards of conduct, written policies, procedures and protocols that verbalize the company’s commitment to compliance.
 - b. Designation of a compliance officer.
 - c. Development and implementation of regular, effective education and training programs.
 - d. The creation and maintenance of an effective line of communication between the compliance officer and all employees.
 - e. The use of audits and/ or other risk evaluation techniques to monitor compliance.

- f. The development of policies and procedures for the investigation of identified instances of noncompliance or misconduct.

B. Title: Integrity of Data Used to Establish or Determine Government Reimbursement

Description: “Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate.”

Guideline: The knowing submission of false, fraudulent, or misleading information is actionable. Under the False Claims Act, a pharmaceutical manufacturer may be liable if government reimbursement information is not reported completely and accurately. Manufacturers’ reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payment, coupons goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchases.

Guideline summary: Pharmaceutical manufacturers are responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes.

C. Title: Kickbacks and Other Illegal Remuneration

Description: “The anti-kickback statute is a criminal prohibition against payments (in any form, whether the payments are direct or indirect) made purposefully to induce or reward the referral or generation of federal health care business.”

Guideline: The offer or payment of anything of value for patient referrals, but also the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or ordering of any item or service reimbursable in whole or part by a federal health care program, is prohibited.

Guideline summary: A manufacturer should identify any remunerative relationship between itself (and its representatives) and persons or entities in a position to generate federal health care business for the manufacturer directly or indirectly.

- i. The arrangement or practice shall not have a potential to interfere with, or skew, clinical decision-making.
- ii. The arrangement or practice shall not undermine the clinical integrity of a formulary process.
- iii. If the arrangement or practice involves providing information to decision-makers, prescribers, or patients, the information must be complete, accurate and not misleading.
- iv. The arrangement or practice shall not have a potential to increase costs to the federal health care programs, beneficiaries, or enrollees.
- v. The arrangement or practice shall not have the potential to be disguised as a discount to circumvent the Medicaid Rebate Program Best Price calculation.
- vi. The arrangement or practice shall not have a potential to increase the risk of overutilization or inappropriate utilization.
- vii. The arrangement or practice shall not raise patient safety or quality of care concerns.

D. Title: Relationships with Purchases and their agents

Description: “Pharmaceutical manufacturers offer purchasers a variety of price concessions and other remuneration to induce the purchase of their products. Inducements offered to purchasers potentially implicate the anti-kickback stature if the purchased products are reimbursable to the purchase, in whole or in part, directly or indirectly, by any of the federal health care programs. Any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to a sale potentially implicates the anti-kickback stature and should be carefully reviewed.”

Guidelines:

- i. Product Support Services: A manufacturer is prohibited, under the anti-kickback statute, from coupling a service that has no independent value in tandem with another service or program that confers a benefit on a referring provider. “For example, the anti-kickback stature would be implicated if a manufacturer were to couple a reimbursement support service with a promise that a purchaser will pay for ordered products only if the purchase is reimbursed by a federal health care program.”

ii. Educational Grants: Pharmaceutical manufacturers sometimes provide grant funding for a wide range of educational activities. Funding that is conditioned, in whole or in part, on the purchase of product implicates the statute, even if the educational or research purpose is legitimate.

Therefore, to reduce the risks that a grant program is used improperly to induce or reward product purchases or to market product inappropriately, manufacturers should separate their grant making functions from their sales and marketing functions. Sales and marketing functions are prohibited from providing grants.

Manufacturers must establish objective criteria for making grants that do not take into account the volume or value of purchases made by, or anticipated from, the grant recipient.

The manufacturer should have no control over the speaker or content of the educational presentation.

Compliance with such procedures should be documented and regularly monitored.

iii. Research Funding: Manufacturers often contract with purchasers of their products to conduct research activities on behalf of the manufacturer on a fee-for-service basis. Manufacturers should develop contracting procedures that clearly separate the awarding of research contracts from marketing.

iv. Other remuneration to purchasers: Any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to a sale may implicate the anti-kickback statute and should be carefully reviewed.

a. Any payments to cover the costs of “converting” from a competitor’s product are prohibited.

b. Selective offers of remuneration (i.e., offers made to some but not all purchasers) may increase potential risk if the selection criteria relate directly or indirectly to the volume or value of business generated, are therefore prohibited.

c. Relationships with formulary committee members should not include any remuneration from a manufacturer or its agents directly or indirectly to a person in position to influence formulary decisions.

d. Formulary placement payments for inclusion in a formulary or for exclusive or restricted formulary status are prohibited.

e. Relationships with physicians and other persons and entities in a position to make or influence referrals should not influence the referral, ordering, or prescribing of the manufacturers' products.

f. If goods or services provided by the manufacturer eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement is prohibited.

g. "Switching" arrangements involve pharmaceutical manufacturers offering physicians or others cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product, is prohibited.

h. Consulting and advisory payments whereby pharmaceutical manufacturers frequently engage physicians and other health care professionals to furnish personal services as consultants or advisers to the manufacturers must be at fair market value to small numbers of physicians for *bona fide* consulting or advisory services.

i. Compensating physicians for services directly or indirectly related to sales and marketing activities such as speaking, certain research, or preceptor or "shadowing" services is prohibited.

j. Payments for detailing (i.e., compensating physicians for time spent listening to sales representatives market pharmaceutical products), is prohibited.

k. Payments for time spent accessing web sites to view or listen to marketing information or perform "research" is prohibited.

v. Business courtesies and Other Gratuities: Pharmaceutical companies and their employees and agents often engage in a number of other arrangements that offer benefits, directly or indirectly, to physicians or others in a position to make or influence referrals.

a. Entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations should be avoided.

- b. Gifts, gratuities, and other business courtesies should be avoided.

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THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)

Code on Interactions with Healthcare Professionals

Background

The Pharmaceutical Manufacturers Association was founded in 1958. Its name was changed to the Pharmaceutical Research and Manufacturers of America in 1994. “Ethical relationships with healthcare professionals are critical to our mission of helping patients by developing and marketing new medicines. This document focuses on interactions with healthcare professionals that relate to the marketing of products. This Code is to reinforce our intention that our interactions with healthcare professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine.”

Code/ guidelines/ regulations for pharmaceutical manufacturers:

1. “Basis of Interactions: Promotional materials provided to healthcare professionals by or on behalf of a company should: (a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between risks and benefits; and (d) be consistent with all other Food and Drug Administration (FDA) requirements governing such communications.”
2. Informational Presentations by Pharmaceutical Company Representatives and Accompanying Meals
 - a. It is appropriate for occasional meals to be offered as a business courtesy to the healthcare professionals as well as members of their staff attending presentations, so long as the presentations provide scientific or education value and the meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to informational communication.
 - b. Any such meals offered in connection with informational presentations made by field sales representatives or their immediate managers should also be limited to in-office or in-hospital settings.
 - c. Inclusion of a healthcare professional’s spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is not appropriate.

- d. Offering “take-out” meals or meals to be eaten without a company representative being present is not appropriate.
- 3. Prohibition on Entertainment and Recreation
 - a. Companies should not provide any entertainment or recreational items.
 - i. Examples include but not limited to: tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips.
 - ii. Such entertainment or recreational benefits should not be offered, regardless of (1) the value of the items; (2) whether the company engages the healthcare professional as a speaker or consultant, or (3) whether the entertainment or recreation is secondary to an educational purpose.
- 4. Pharmaceutical Company Support for Continuing Medical Education
 - a. Giving of any subsidy directly to a healthcare professional by a company is prohibited.
 - b. Any financial support should be given to the CME provider, which, in turn, can use the money to reduce the overall CME registration fee for all participants.
 - c. The company is prohibited to provide any advice or guidance to the CME provider, even if asked by the provider, regarding the content or faculty for a particular CME program funded by the company.
 - d. Financial support is prohibited for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME.
 - e. Funding should not be offered to compensate for the time spent by healthcare professionals participating in the CME event.
 - f. A company should not provide meals directly at CME events, except that a CME provider at its own discretion may apply the financial support provided by a company for CME event to provide meals for all participants.
- 5. Pharmaceutical Company Support for Third-Party Educational or Professional Meetings
 - a. Any subsidy or financial support for professional meetings may not be provided to a healthcare professional.
 - b. Financial support for professional meetings should be given directly to the conference’s sponsor, which, in turn, can use the money to reduce the overall conference registration fee for all attendees.
 - c. When companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conference and may not be influenced by the sponsoring company.
 - d. Financial support for the costs of travel, lodging, or other personal expenses is prohibited.
- 6. Consultants
 - a. Consulting agreements are prohibited to serve as either inducements or rewards for prescribing or recommending a particular medicine or course of treatment.
 - b. A written contract must specify the nature of the consulting services to be provided and the basis for payment of those services.
 - c. A legitimate need for the consulting services must be clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants.

- d. The criteria for selecting consultants must be directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria.
- e. It is required that the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose.
- f. The retaining company must maintain records concerning and makes appropriate use of the services provided by consultants.
- g. The venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting; specifically, resorts are not appropriate venues.
- h. Companies are prohibited to provide recreational or entertainment events in conjunction with consultant/ educational meetings.
- i. It is prohibited to pay honoraria or travel or lodging expenses to non-faculty and non-consultant healthcare professional attendees at company-sponsored meetings, including attendees who participate in interactive sessions.

7. Speaker Programs and Speaker Training Meetings

- a. Company decisions regarding the selection or retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation.
- b. Each company should cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements.
- c. Each company should develop policies addressing the appropriate use of speakers, including utilization of speakers after training and the appropriate number of engagements for any particular speaker over time.
- d. Speakers and their materials must clearly identify the company that is sponsoring the presentation.
- e. Companies must monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines.

8. Healthcare Professionals Who Are Members of Committees That Set Formularies of Develop Clinical Practice Guidelines

- a. Companies must require any healthcare professional who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the existence and nature of his or her relationship with the company.

9. Scholarships and Educational Funds

- a. Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend educational conferences may only be offered by the academic or training institution.

10. Prohibition of Non-Educational and Practice-Related Items

- a. Providing items for healthcare professionals' use that do not advance disease or treatment education are prohibited. Examples include but are not limited to: pens, note pads, mugs and similar "reminder" items with company or product logos.

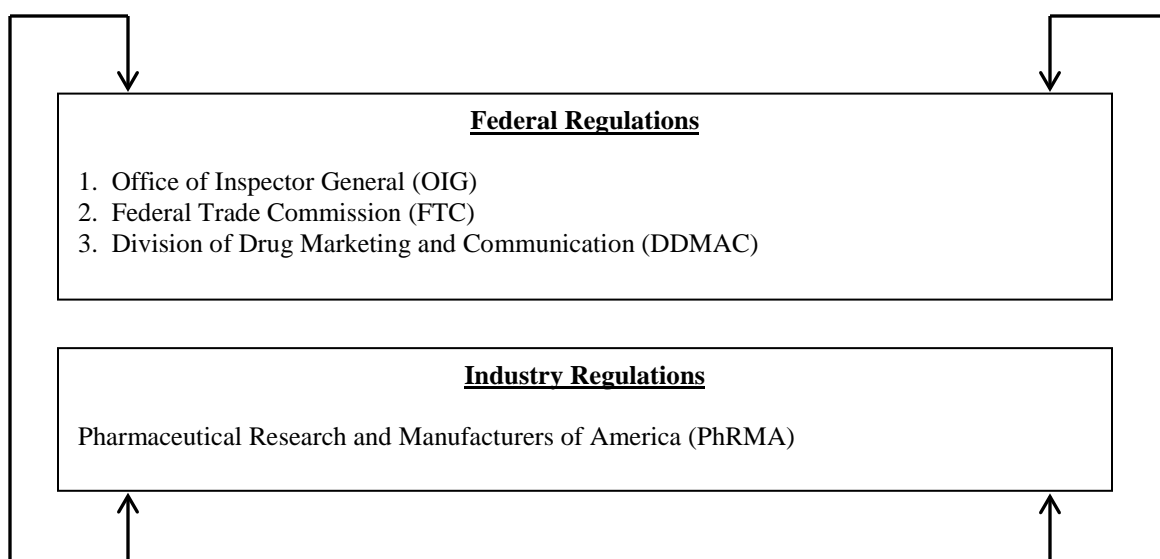
- b. Items intended for personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) are prohibited.
- c. Payments in cash or cash equivalents (such as gift certificates) are prohibited.

11. Educational Items

- a. Items designed primarily for education of patients or healthcare professionals must be \$100 or less in value.
- b. Items designed primarily for the education of patients or healthcare professionals should not be offered on more than an occasional basis.

12. Independence and Decision Making

- a. No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products.

APPENDIX 4**Final Typology for Source of Regulations**

APPENDIX 5

Table of Regulations
(In ascending order by number)

Regulation Number	Description of Regulation
1	The manufacturer, sales representatives, or other agents of the company, may not offer payment or anything of value for patient referrals or in return for purchasing (prescriptions)
2	Manufacturer should identify any remunerative relationship between itself (and its representatives) and persons or entities in a position to generate federal health care business for the manufacturer directly or indirectly
3	When providing information to decision-makers, prescribers, or patients, the information must be complete, accurate and not misleading
4	Manufacturer is prohibited from coupling a service that has no independent value in tandem with another service or program that confers a benefit on a referring provider
5	Sales and marketing functions are prohibited from providing grants, nor can it be involved in any aspect of grant making
6	Manufacturer should have no control over the speaker or content of the educational presentation
7	Manufacturer must document grant making and educational presentation procedures and regularly monitor
8	Any payments to cover the costs of "converting" from a competitor's product is prohibited
9	Selective offers of remuneration (i.e., offers made to some but not all purchasers) are prohibited
10	Relationships with formulary committee members should not include any remuneration from a manufacturer or its agents, nor to influence formulary decisions which are exclusive or restricted status
11	Relationships with physicians and other persons and entities in a position to make or influence referrals should not influence the referral, ordering, or prescribing of the manufacturers products

12	If goods or services provided by the manufacturers eliminate an expense that the physician would have otherwise incurred (i.e., have independent value to the physician), or if items or services are sold to a physician at less than their fair market value, the arrangement is prohibited
13	"Switching" arrangements involve pharmaceutical manufacturers offering physicians or others cash payments or other benefits each time a patient's prescription is changed to the manufacturer's product from a competing product, is prohibited
14	Consulting and advisory payments whereby pharmaceutical manufacturers frequently engage physicians and other health care professionals to furnish personal services as consultants or advisers to the manufacturers must be at fair market value to small numbers of physicians for bona fide consulting or advisory services
15	Compensating physicians for services directly or indirectly related to sales and marketing activities such as speaking, certain research, or preceptor or "shadowing" services is prohibited
16	Payments for detailing (i.e., compensating physicians for time spent listening to sales representatives market pharmaceutical products), is prohibited
17	Payments for time spent accessing web sites to view or listen to marketing information or perform "research" is prohibited
18	Entertainment, recreation, travel and meals in association with information or marketing/ sales presentations are prohibited
19	Gifts, gratuities, and other business courtesies are prohibited
20	Promotional materials provided to healthcare professionals by or on behalf of a company should make properly substantiated claims and reflect the balance between risks and benefits
21	Promotional materials provided to healthcare professionals by or on behalf of a company should be consistent with all other Food and Drug Administration (FDA) requirements governing such communications
22	Occasional meals may be offered as a business courtesy to healthcare professionals (including members of their staff) attending sales/ marketing presentations provided the meal is modest as judged by local standards

23	Occasional meals may be offered as a business courtesy to healthcare professionals (including members of their staff) attending sales/ marketing presentations as long as the meeting is not part of an entertainment or recreational event
24	Occasional meals may be offered as a business courtesy to healthcare professionals (including members of their staff) attending sales/ marketing presentations so long as the presentations provide scientific or educational value.
25	Meals offered in connection with informational presentations made by field sales representatives or their immediate managers should also be limited to in-office or in-hospital settings
26	Inclusion of a healthcare professional's spouse or other guest in a meal accompanying an informational presentation made by or on behalf of a company is prohibited
27	Offering "take-out" meals or meals to be eaten without a company representative being present is prohibited
28	Companies are prohibited from providing any entertainment or recreational items including tickets to theatre or sporting events, sporting equipment, or leisure and vacation trips
29	Giving of any subsidy directly to a healthcare professional by a company is prohibited
30	Any financial support should be given to the CME provider, which, in turn, can use the money to reduce the overall CME registration fee for all participants
31	The company is prohibited to provide any advice or guidance to the CME provider, even if asked by the provider, regarding the content or faculty for a particularly CME program funded by the company
32	Financial support is prohibited for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME
33	Funding should not be offered to compensate for the time spent by healthcare professionals participating in the CME event
34	A company should not provide meals directly at CME events, except that a CME provider at its own discretion may apply the financial support provided by a company for CME event to provide meals for all participants
35	Any subsidy or financial support for professional meetings may not be provided to a healthcare professional

36	Financial support for professional meetings should be given directly to the conference's sponsor, which, in turn, can use the money to reduce the overall conference registration fee for all attendees
37	When companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conference and may not be influence by the sponsoring company
38	Financial support for the costs of travel, lodging, or other personal expenses are prohibited
39	Consulting agreements are prohibited to serve as either inducements or rewards for prescribing or recommending a particular medicine or course of treatment
40	A written contract must specify the nature of the consulting services to be provided and the basis for payment of those services
41	A legitimate need for the consulting services must be clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants
42	The criteria for selecting consultants must be directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria
43	It is required that the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose
44	The retaining company must maintain records concerning and makes appropriate use of the services provided by consultants
45	The venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting; specifically, resorts are not appropriate venues
46	Companies are prohibited to provide recreational or entertainment events in conjunction with consultant/ educational meetings
47	It is prohibited to pay honoraria or travel or lodging expenses to non-faculty and non-consultant healthcare professional attendees at company-sponsored meetings, including attendees who participate in interactive sessions

48	Company decisions regarding the selection or retention of healthcare professionals as speakers should be made based on defined criteria such as general medical expertise and reputation
49	Each company should cap the total amount of annual compensation it will pay to an individual healthcare professional in connection with all speaking arrangements
50	Each company should develop policies addressing the appropriate use of speakers, including utilization of speakers after training and the appropriate number of engagements for any particular speaker over time
51	Speakers and their materials must clearly identify the company that is sponsoring the presentation
52	Companies must monitor speaker programs for compliance with FDA regulatory requirements for communications on behalf of the company about its medicines
53	Companies must require any healthcare professional who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the existence and nature of his or her relationship with the company
54	Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend educational conferences may only be offered by the academic or training institution
55	Providing items for healthcare professionals' use that do not advance disease or treatment education is prohibited. Examples include but are not limited to: pens, note pads, mugs and similar "reminder" items with company or product logos
56	Items intended for personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) are prohibited
57	Payments in cash or cash equivalents (such as gift certificates) are prohibited
58	Items designed primarily for education of patients or healthcare professionals must be \$100 or less in value
59	Items designed primarily for the education of patients or healthcare professionals should not be offered on more than an occasional basis

60	No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products
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APPENDIX 6

Selling Activities

Relationship Building (Reid, Plank, and Minton 1997)

- x1: Ability to ask probing questions
- x2: Listened to customer
- x3: Ability to make a charismatic presentation
- x4: Ability to work well with other people who are involved in the purchase

(Adapted from industry interviews and focus groups)

- x16: Follow up with customer

Getting to Buy (Reid, Plank, and Minton 1997)

- x5: Gain participation and got customer involved in the sales presentation
- x6: Ability to use analogies and similes in his/her presentation to help customer see how it relates to his/her situation
- x7: Ability to link his/her product/service attributes to customer needs
- x8: Could differentiate his/her product/service from the competition
- x9: Ability to do “homework” on customer
- x10: Ability to handle objections raised by customer

Planning

(Moncrief, Marshall, and Lassk 2006)

- x11: Search out new leads
- x12: Pre-call planning/ targeting
- x17: Administrative activities/ documentation

(Adapted from industry interviews and focus groups)

- x13: Conduct targeting activities
- x14: Designing sales plan
- x15: Business planning

APPENDIX 7

Survey Cover Letter

Research Study Title: The Effect of Regulation on Selling Activities

Primary Investigator: John F. Riggs, D.B.A., Doctoral Candidate, A.B.D.

Dear Participant,

I am inviting you participate in a research project to study the effect of regulation on selling activities. Along with this letter is a short questionnaire that asks a variety of questions about how you perceive specific regulations affect your selling activities. The questionnaire contains only twenty (20) items and will take about 15 minutes to complete. I guarantee that your responses will not be identified with you personally, are blinded, and completely anonymous.

The results of this project will be used to complete my doctoral dissertation. Through your participation I hope to develop a taxonomy (classification scheme) of regulations that accurately reflects their effect on selling activities by pharmaceutical sales people. I hope to share my results by publishing them in a scientific journal as well as various public press outlets.

This project has been approved by the Institutional Review Board (IRB) at Kennesaw State University, Kennesaw, Georgia.

Sincerely,

John F. Riggs
Doctor of Business Administration, Doctoral Candidate, A.B.D.
Kennesaw State University
Email: 610ksudba@comcast.net

Survey Version #1

Regs and Sales 1

Thank you for taking the time to complete this survey. This survey should only take about 15 minutes of your time. Your answers will be completely "blinded" and anonymous.

1. Please select your gender

- ☐ Female
- ☐ Male

2. Please select the range that describes your current age

- ☐ 18 - 25 years
- ☐ 26 - 35 years
- ☐ 36 - 45 years
- ☐ 46 and older

3. Please select your highest level of education

- ☐ Associates Degree
- ☐ Bachelors Degree
- ☐ Masters Degree
- ☐ Doctoral Degree

Other (be sure to include any licenses, medical or otherwise; please specify)

4. How many years of selling experience do you have? Please provide total years...all industries.

- ☐ Less than 1 year
- ☐ 1 - 5 years
- ☐ 6 - 10 years
- ☐ 11 - 15 years
- ☐ 16 - 20 years
- ☐ More than 20 years

Regs and Sales 1**5. How long have you worked in the pharmaceutical industry?**

- ☐ Less than 1 year
- ☐ 1 - 5 years
- ☐ 6 - 10 years
- ☐ 11-15 years
- ☐ 16 - 20 years
- ☐ More than 20 years

6. How long have you worked for your current company?

- ☐ Less than 1 year
- ☐ 1 - 5 years
- ☐ 6 - 10 years
- ☐ 11 - 15 years
- ☐ 16 - 20 years
- ☐ More than 20 years

7. Please select the region where you primarily sell.

- ☐ Northeast U.S.
- ☐ Southeast U.S.
- ☐ Caribbean
- ☐ Central U.S.
- ☐ North Central U.S.
- ☐ Southwestern U.S.
- ☐ Northwestern U.S.
- ☐ Nationally (entire U.S.)

Regs and Sales 1**8. What was your major in college?**

- ☐ Marketing
- ☐ Finance
- ☐ Accounting
- ☐ Sales
- ☐ Education
- ☐ Psychology
- ☐ Health Related Professions
- ☐ Computer Science

Other (please specify)

Survey Version #2

Regs and Sales 2

1.

Thank you for taking the time to complete this survey. This survey should only take about 15 minutes of your time. Your answers will be completely "blinded" and anonymous.

In order to allow us to better understand your perspective and perceptions, the following questions are needed as general background information.

1. Please select your gender

☐ Female

☐ Male

2. Please select the range that describes your current age

☐ 18 - 25 years

☐ 26 - 35 years

☐ 36 - 45 years

☐ 46 and older

3. Please select your highest level of education

☐ Associates Degree

☐ Bachelors Degree

☐ Masters Degree

☐ Doctoral Degree

Other (be sure to include any licenses, medical or otherwise; please specify)

4. How many years of selling experience do you have? Please provide total years...all industries

☐ Less than 1 year

☐ 1 - 5 years

☐ 6 - 10 years

☐ 11 - 15 years

☐ 16 - 20 years

☐ More than 20 years

Regs and Sales 2**5. How long have you worked in the pharmaceutical industry?**

- ☐ Less than 1 year
- ☐ 1 - 5 years
- ☐ 6 - 10 years
- ☐ 11 - 15 years
- ☐ 16 - 20 years
- ☐ More than 20 years

6. How long have you worked for your current company?

- ☐ Less than 1 year
- ☐ 1 - 5 years
- ☐ 6 - 10 years
- ☐ 11 - 15 years
- ☐ 16 - 20 years
- ☐ More than 20 years

7. Please select the region where you primarily sell (pick one).

- ☐ Northeast U.S.
- ☐ Southeast U.S.
- ☐ Caribbean
- ☐ Central U.S.
- ☐ North Central U.S.
- ☐ Southwest U.S.
- ☐ Northwest U.S.
- ☐ Nationally (entire U.S.)

Other (please specify)

Regs and Sales 2**8. What was your major in college?**

- ☐ Marketing
- ☐ Finance
- ☐ Accounting
- ☐ Sales
- ☐ Education
- ☐ Psychology
- ☐ Health Related Professions
- ☐ Computer Science

Other (please specify)

Survey Version #3

Regs and Sales 3

Thank you for taking the time to complete this survey. This survey should only take about 15 minutes of your time. Your answers will be completely "blinded" and anonymous.

1. Please select your gender

- ☐ Female
- ☐ Male

2. Please select the range that describes your current age

- ☐ 18 - 25 years
- ☐ 26 - 35 years
- ☐ 36 - 45 years
- ☐ 46 and older

3. Please select your highest level of education

- ☐ Associates Degree
- ☐ Bachelors Degree
- ☐ Masters Degree
- ☐ Doctoral Degree

Other (be sure to include any licenses, medical or otherwise; please specify)

4. How many years of selling experience do you have? Please provide total years...all industries.

- ☐ Less than 1 year
- ☐ 1 - 5 years
- ☐ 6 - 10 years
- ☐ 11 - 15 years
- ☐ 16 - 20 years
- ☐ More than 20 years

Regs and Sales 3**5. How long have you worked in the pharmaceutical industry?**

- ☐ Less than 1 year
- ☐ 1 - 5 years
- ☐ 6 - 10 years
- ☐ 11-15 years
- ☐ 16 - 20 years
- ☐ More than 20 years

6. How long have you worked for your current company?

- ☐ Less than 1 year
- ☐ 1 - 5 years
- ☐ 6 - 10 years
- ☐ 11 - 15 years
- ☐ 16 - 20 years
- ☐ More than 20 years

7. Please select the region where you primarily sell.

- ☐ Northeast U.S.
- ☐ Southeast U.S.
- ☐ Caribbean
- ☐ Central U.S.
- ☐ North Central U.S.
- ☐ Southwestern U.S.
- ☐ Northwestern U.S.
- ☐ Nationally (entire U.S.)

Regs and Sales 3**8. What was your major in college?**

- ☐ Marketing
- ☐ Finance
- ☐ Accounting
- ☐ Sales
- ☐ Education
- ☐ Psychology
- ☐ Health Related Professions
- ☐ Computer Science

Other (please specify)

APPENDIX 8

Factor Analysis Final Groupings

Factor 1 Customer Relationships through Communication
x1: Ability to ask probing questions x2: Listened to customer x3: Ability to make a charismatic presentation x4: Ability to work well with other people who are involved in the purchase x16: Follow up with customer
Factor 2 Core Selling Skills
x5: Gain participation and got customer involved in the sales presentation x6: Ability to use analogies and similes in his/her presentation to help customer see how it relates to his/her situation x7: Ability to link his/her product/service attributes to customer needs x8: Could differentiate his/her product/service from the competition x9: Ability to do “homework” on customer x10: Ability to handle objections raised by customer
Factor 3 Planning
x11: Search out new leads x12: Pre-call planning/ targeting x13: Conduct targeting activities x14: Designing sales plan